

US3522299 (Prod: Henry Ford Health System)

Generated By: KC Joubran

Generated On: 10 Jun 2021 07:59:48

All time stamps listed in this document are displayed in GMT

US3522299

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

[Participant ID](#)

US3522299

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

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Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	58
Age Units	YEARS
Age (Derived)	58
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) 05 Mar 2021 15:45:40

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Date of Informed Consent (<i>dd MMM yyyy</i>)	24 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) 05 Mar 2021 15:45:40

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 15:45:40

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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) 05 Mar 2021 15:45:40

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Condition	ASTHMA - MILD ALLERGY MEDIATED
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Condition	UNDERACTIVE THYROID
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Condition	LYMPHATIC SYSTEM DAMAGE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Condition	OBESITY BMI > 40
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Condition	POST MENOPAUSE
Start date (dd MMM yyyy)	UN DEC 2017
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)	DEC 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Condition	BILATERAL LOWER EXTREMITY SWELLING
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Condition	ROSACEA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Condition	ALLERGIES- SEASONAL
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3522299

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	07:47 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 07:47
Height (<i>xxx.x</i>)	62 in
Weight (<i>xxx.x</i>)	247.9 lb
BMI (<i>xxx.x</i>)	45.43631 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) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 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) 05 Mar 2021 15:45:40

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Date of assessment (*dd MMM yyyy*) 24 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN DEC 2016

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 15:45:40

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 15:45:40

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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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

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

Visit date (dd MMM yyyy)	24 AUG 2020
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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	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 144532

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) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

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) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

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)	24 AUG 2020
Time of assessment (00:00-23:59)	07:47 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 07:47
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

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)	24 AUG 2020
Time of assessment (00:00-23:59)	09:45 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 09:45
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	170 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

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) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

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) 24 AUG 2020

What was the treatment time? (00:00-23:59) 09:15 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 09:15

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) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 AUG 2020
Collection time (00:00-23:59)	09:10 (24 HR)
Collection date and time (derived)	24 AUG 2020 09:10

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:05	24 AUG 2020 08:05
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

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: 10 Jun 2021 07:59:48

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

24 AUG 2020 10:01

PC Open Date & Time

24 AUG 2020 09:35

PC Close Date & Time

24 AUG 2020 12:05

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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 98.5 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 24 AUG 2020 17:57

PC Open Date & Time 24 AUG 2020 13:00

PC Close Date & Time 25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:48

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

25 AUG 2020 17:57

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

26 AUG 2020 18:04

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:48

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

98.2 °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

27 AUG 2020 18:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

28 AUG 2020 17:59

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

29 AUG 2020 17:56

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 18:07

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 10:00

PC Open Date & Time

24 AUG 2020 09:35

PC Close Date & Time

24 AUG 2020 12:05

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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

24 AUG 2020 17:57

PC Open Date & Time

24 AUG 2020 13:00

PC Close Date & Time

25 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

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

25 AUG 2020 17:58

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

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

26 AUG 2020 18:04

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

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

27 AUG 2020 18:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:48

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

28 AUG 2020 17:59

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:48

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

29 AUG 2020 17:56

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:48

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

30 AUG 2020 18:07

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 10:00
PC Open Date & Time	24 AUG 2020 09:35
PC Close Date & Time	24 AUG 2020 12:05

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 17:58
PC Open Date & Time	24 AUG 2020 13:00
PC Close Date & Time	25 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

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 ☒

PRODUCTION RELEASE (v12.003

50 of 2415

EAB) (1725)

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 17:58
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

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 ☒

PRODUCTION RELEASE (v12.003

52 of 2415

EAB) (1725)

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 18:05
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

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

54 of 2415

EAB) (1725)

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 18:01
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

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

56 of 2415

EAB) (1725)

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 18:00
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

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 ☒

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 17:57
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

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

60 of 2415

EAB) (1725)

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 18:08
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3522299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 AUG 2020

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

Comments REPORTED HA AND CHILLS
WHICH IS NORMAL PER
If Contact Not Made, please provide Comments BASELINE, HOWEVER PT
REPORTED SYMPTOMS WERE
EXACERBATED AFTER
INJECTION. SYMPTOMS HAVE
SINCE RESOLVED. NO COVID
CONTACT.

US3522299

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 SEP 2020

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

Comments
If Contact Not Made, please provide Comments
NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK.

US3522299

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 SEP 2020

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

Comments "NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK."

If Contact Not Made, please provide Comments

US3522299

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Apr 2021 16:12:14

Generated On: 10 Jun 2021 07:59:48

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)	21 SEP 2020
Time of assessment (00:00-23:59)	08:27 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 08:27
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	179 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Apr 2021 16:12:14

Generated On: 10 Jun 2021 07:59:48

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)	21 SEP 2020
Time of assessment (00:00-23:59)	09:20 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 09:20
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	169 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3522299

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3522299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 08:50 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 08:50

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

US3522299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 SEP 2020
Collection time (00:00-23:59)	08:45 (24 HR)
Collection date and time (derived)	21 SEP 2020 08:45

US3522299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:49	21 SEP 2020 08:49
Nasopharyngeal Swab 2	No		

US3522299

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 09:22

PC Open Date & Time

21 SEP 2020 09:10

PC Close Date & Time

21 SEP 2020 11:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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 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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 21 SEP 2020 18:04

PC Open Date & Time 21 SEP 2020 12:35

PC Close Date & Time 22 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	22 SEP 2020 17:57
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:48

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

99.9 °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

23 SEP 2020 18:15

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 18:06

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 18:04

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 18:20

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:48

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

98.7 °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

27 SEP 2020 18:27

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 09:23

PC Open Date & Time

21 SEP 2020 09:10

PC Close Date & Time

21 SEP 2020 11:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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

21 SEP 2020 18:04

PC Open Date & Time

21 SEP 2020 12:35

PC Close Date & Time

22 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

4

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

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

Yes ☐

No ☒

Please record - **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

22 SEP 2020 17:58

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

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 ☐

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

3

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

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

Yes ☐

No ☒

Please record - **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

23 SEP 2020 18:16

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

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 ☐

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

3

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

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

Yes ☐

No ☒

Please record - **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

24 SEP 2020 18:07

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:48

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

25 SEP 2020 18:04

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:48

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

26 SEP 2020 18:21

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:48

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

27 SEP 2020 18:27

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 09:23
PC Open Date & Time	21 SEP 2020 09:10
PC Close Date & Time	21 SEP 2020 11:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 18:05
PC Open Date & Time	21 SEP 2020 12:35
PC Close Date & Time	22 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

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 ☒

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 17:59
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

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 ☒

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 18:16
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

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 ☒

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 18:07
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

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

102 of 2415

EAB) (1725)

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 18:05
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

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

104 of 2415

EAB) (1725)

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 18:21
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

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)

106 of 2415

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 18:28
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3522299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 SEP 2020

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

Comments AFTERNOON OF INJECTION
TOOK 650 MG OF TYLENOL.
If Contact Not Made, please provide Comments HEADACHE SUBSIDED. EDIARY
MATCHED,

US3522299

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 06 OCT 2020

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

Comments SEE SOURCE

If Contact Not Made, please provide Comments

US3522299

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 OCT 2020

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

Comments
If Contact Not Made, please provide Comments
PATIENT IS STILL HAVING
MILD HEADACHES, MAY BE
RELATED TO SINUS PRESSURE
CONTINUING TO TAKE
TYLENOL, 1-2 TIMES PER DAY
AS NEEDED, FOR
HEADACHE..FLU SHOT
09-OCT-2020

US3522299

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3522299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	07:36 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 07:36
Temperature (xxx.x)	98 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522299

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

US3522299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 OCT 2020
Collection time (00:00-23:59)	07:50 (24 HR)
Collection date and time (derived)	23 OCT 2020 07:50

US3522299

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:41:30

Generated On: 10 Jun 2021 07:59:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 ☒

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 OCT 2020 11:35:49

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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

03 NOV 2020 12:41:08

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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	09 NOV 2020 13:33:31
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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"/>
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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 checked="" 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 checked="" type="radio"/>
Date and time of submission	25 NOV 2020 07:07:36
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 18:57:12

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 09:58:31

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 type="radio"/> Yes <input checked="" 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"/>
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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 checked="" 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 checked="" type="radio"/>
Date and time of submission	16 DEC 2020 04:56:39
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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

23 DEC 2020 06:39:09

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 <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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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

06 JAN 2021 13:07:46

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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

15 JAN 2021 13:47:22

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 18:49:52

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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	07 FEB 2021 19:27:14
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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

10 FEB 2021 14:06:15

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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	17 FEB 2021 17:27:41
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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	27 FEB 2021 20:09:17
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 05:44:15

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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	10 MAR 2021 13:14:47
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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

17 MAR 2021 10:41:42

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 <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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 type="radio"/> Yes <input checked="" 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"/>
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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 checked="" 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 checked="" type="radio"/>
Date and time of submission	31 MAR 2021 19:50:58
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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

08 APR 2021 08:46:25

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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

15 APR 2021 12:35:59

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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

21 APR 2021 11:58:52

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 <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	28 APR 2021 16:41:51
Patient Cloud Open Date & Time	28 APR 2021 00:01
Patient Cloud Close Date & Time	02 MAY 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 257

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

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 <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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 271

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

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 <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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01
Patient Cloud Close Date & Time	30 MAY 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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="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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 292

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

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 306

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

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	27 JUN 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 <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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	04 JUL 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
Patient Cloud Close Date & Time	18 JUL 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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="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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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="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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 355

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

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 <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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	22 AUG 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	29 AUG 2021 23:59
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US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 <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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 <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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	12 SEP 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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="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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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="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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	03 OCT 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	17 OCT 2021 23:59
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US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	24 OCT 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 <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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	31 OCT 2021 23:59
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US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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="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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	14 NOV 2021 23:59
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US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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="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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 474

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

Fever (Temperature \geq 100.4°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 ☐

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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="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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 502

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

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 516

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

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 523

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

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 <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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 586

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

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	17 APR 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	24 APR 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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="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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 628

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

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 <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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 <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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 649

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

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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°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 ☐

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	12 JUN 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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	29 JUN 2022 00:01
Patient Cloud Close Date & Time	03 JUL 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	24 JUL 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 705

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

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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="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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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="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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 733

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

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	28 AUG 2022 23:59
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US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	25 SEP 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

DAY 768

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

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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	05 OCT 2022 00:01
Patient Cloud Close Date & Time	09 OCT 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 <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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	23 OCT 2022 23:59

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3522299

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 07:59:48

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 20:09:33

US3522299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 NOV 2020

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

Comments
If Contact Not Made, please provide Comments
NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK.

US3522299

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK.

If Contact Not Made, please provide Comments

US3522299

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522299

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 JAN 2021

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

Comments BLOOD PRESSURE HAS BEEN
IMPROVING, TODAY WAS
140S/80 AND WILL BE
FOLLOWING UP WITH PCP ON
22 JAN 2021. OTHERWISE, NO
OTHER ONGOING OR NEW AE
REPORTED; NO OTHER HEALTH
CHANGES OR COVID-19
EXPOSURES

If Contact Not Made, please provide Comments

US3522299

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522299

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 FEB 2021

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

Comments NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK

If Contact Not Made, please provide Comments

US3522299

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522299

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 18:13:12

Generated On: 10 Jun 2021 07:59:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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	VISIT4

US3522299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 11:38:53

Generated On: 10 Jun 2021 07:59:48

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) _____

US3522299

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 18:13:12

Generated On: 10 Jun 2021 07:59:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 MAR 2021

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

US3522299

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 18:13:12

Generated On: 10 Jun 2021 07:59:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 MAR 2021
Collection time (00:00-23:59)	08:12 (24 HR)
Collection date and time (derived)	19 MAR 2021 08:12

US3522299

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 18:13:12

Generated On: 10 Jun 2021 07:59:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:12:14

Generated On: 10 Jun 2021 07:59:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

RECOVERING WELL FROM
OPEN VENTRAL HERNIA
SURGERY. LAST FOLLOW-UP
WITH PCP ON 16 APR 2021.
POST-OP, DEVELOPED DEEP
SOFT TISSUE INFECTION,
PRESCRIBED 10-DAY COURSE
OF CIPROFLOXACIN 500 MG

US3522299

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:12:14

Generated On: 10 Jun 2021 07:59:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522299

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

US3522299

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3522299

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:59:48

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"/>

US3522299

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 07:59:48

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3522299

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

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

Visit date (dd MMM yyyy)	15 JAN 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	UNBLND_DECIDE
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US3522299

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 18:13:12

Generated On: 10 Jun 2021 07:59:48

Date of updated informed consent (*dd MMM yyyy*) 15 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (*dd MMM yyyy*) 15 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3522299

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00-23:59)	09:38 (24 HR)
Collection date and time (derived)	15 JAN 2021 09:38

US3522299

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00 - 23:59)	09:38
Collection Date and Time (derived)	15 JAN 2021 09:38

US3522299

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

AEID	
Adverse event	HYPERTENSION
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)	20 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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 type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

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 checked="" type="radio"/> Dose Delayed <input 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	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

PER UNSCHEDULED
COMMUNICATION 25-NOV-2020:
PT SAW PCP 20 NOV 2020 AND
DISCOVERED BP OF 160/112. PT
STATES HER BP HAS BEEN
ELEVATED IN THE PAST BUT
WAS NOT HIGH ENOUGH TO
WORRY ABOUT. WAS STARTED
ON AMLODIPINE 5 MG DAILY.
PT STATES PCP WANTS HER TO
CONTINUE TAKING THIS
WHILE AWAITING SOME LAB
WORK AND COULD POSSIBLY
CHANGE MEDICATION
FOLLOWING. PT VERBALIZED
UNDERSTANDING AND WILL
REACH OUT TO STUDY STAFF
WITH ANY CHANGES

PER UNSCHEDULED
COMMUNICATION 16-DEC-2020:
"SINCE THE LAST UPDATE, MY
PCP HAS ADDED ANOTHER
MEDICATION FOR MY BLOOD
PRESSURE. LOSARTAN
POTASSIUM 25MG 1 TAB PER
DAY WAS STARTED ON
12/10/2020."
UPDATE 19 JAN 2021: BP IS
IMPROVING (TODAY WAS IN
140S/80) AND WILL FOLLOW UP
WITH PCP ON 22 JAN 2021

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

AEID	USA-US131-2021-MRNA-1273-P30 1000014
Adverse event	VENTRAL HERNIA WITH INCARCERATED SMALL BOWEL
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)	23 MAR 2021
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)	25 MAR 2021
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)	24 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	26 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

PARTICIPANT STARTED ABDOMINAL PAIN AND VOMITING ON 3/23 AND WENT TO ED ON 3/24. PARTICIPANT FOUND TO HAVE A VENTRAL HERNIA (CONFIRMED BY CT ON 24 MAR 2021 WHICH SHOWED OBSTRUCTING VENTRAL WALL HERNIA CAUSING SMALL BOWEL OBSTRUCTION) THAT WAS NOT REDUCIBLE. CBC ON 24 MAR 2021 SHOWED A SLIGHT INCREASE IN ABSOLUTE NEUTROPHILS (7.8 K/UL) AND DECREASE IN LYMPHOCYTES (1.00 K/UL). PATIENT TESTED NEGATIVE FOR COVID-19 ON 24 MAR 2021. PARTICIPANT HAD OPEN VENTRAL HERNIA REDUCTION WITH SUCCESSFUL REDUCTION AND HERNIA REPAIR ON 24 MAR 2021. SURGICAL PERITONEAL FLUID AND TISSUE WERE BENIGN. PATIENT DISCHARGED ON 3/26 TO RECOVER AT HOME.

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)	0

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

AEID

Adverse event

ABDOMINAL
SEROMA-SURGICAL
WOUND(PSEUDOMONAS
AERUGINOSA AND PROTEUS
MIRABILIS)

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) 5 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☒
No ☐

If not Ongoing, end date (dd MMM yyyy)

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 ☐

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Folder: Adverse Events

Form: Adverse Events (4)

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

POST-OP, DEVELOPED
SURGICAL WOUND
ABDOMINAL SEROMA WHICH
WAS SWABED FOR CULTURE
ON 05 AP 2021 AND FOUND TO
BE INFECTIOUS (PROTEUS
MIRABILIS AND
PSEUDOMONAS AERUGINOSA),
PRESCRIBED 10-DAY COURSE
OF CIPROFLOXACIN 500 MG
TWICE DAILY, TAKEN FROM 12
APR 2021 AND ENDS 21 APR
2021.

Serious Adverse Event Derived (CSA Programming Field Only)	0
--	---

Medically Attended AE Derived (CSA Programming Field Only)	1
--	---

Admitted to ICU Derived (CSA Programming Field Only)	
--	--

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 15:45:40

Generated On: 10 Jun 2021 07:59:48

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 (2)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication UNDERACTIVE THYROID

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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) _____		
Start date completely unknown		True
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 (3)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication ROSCAE

Dose per administration 50-100

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) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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) _____		
Start date completely unknown		True
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) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 180

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) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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 (5)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 650

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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)		21 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PAIN DUE TO SWELLING IN
LOWER BILATERAL
EXTREMITIES

Dose per administration 500

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 (6)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN OCT 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 (7)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication INFLUENZA QUAD VACCINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF 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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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)	9 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		9 OCT 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 (8)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 1300

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) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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)	24 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) 24 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 (9)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 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 (9)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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)	20 NOV 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 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication LOSARTAN POTASSIUM

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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 JAN 2021	
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 (12)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 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 (12)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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)		15 FEB 2021
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)		2
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 (13)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication POLYETHYLENE GLYCOL

Prophylaxis Yes ☐
No ☒

Indication VENTRAL HERNIA SURGERY

Dose per administration 17

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 (13)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	Intramuscular	<input 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)	26 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	29 MAR 2021	
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 (14)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication POST SURGICAL PAIN

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

PRN Q6

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) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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 MAR 2021
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 (15)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication VENTRAL HERNIA PAIN

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	Intramuscular	<input 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 checked="" 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)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	24 MAR 2021	
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 (16)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication POST SURGICAL PAIN

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 (16)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication NAUSEA RELATED TO
VENTRAL HERNIA

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

TWICE AS NEEDED

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 MAR 2021
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 (18)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication CITRIC ACID SODIUM CITRATE

Prophylaxis Yes ☐
No ☒

Indication NAUSEAS FROM VENTRAL
HERNIA

Dose per administration 30

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 (18)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 MAR 2021
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 (19)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication NAUSEA FROM VENTRAL
HERNIA

Dose per administration 20

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 (19)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 MAR 2021
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 (20)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication CEFAZOLIN

Prophylaxis Yes ☒
No ☐

Indication PRE SURGICAL PROPHYLAXIS

Dose per administration 2

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 (20)

Data signed: (b) (4) 30 Apr 2021 16:29:57

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	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)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 24 MAR 2021		
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 (23)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication HYDROCODONE-ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication POST SURGICAL PAIN

Dose per administration 5-325

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

PRN Q6

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 30 Apr 2021 16:29:57

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	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)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 MAR 2021
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 (24)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication POST SURGICAL PAIN

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 (24)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 24 MAR 2021		
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 (25)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication POST SURGICAL PAIN

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 Q6

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	26 MAR 2021	
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 (26)

Data signed: (b) (4) 30 Apr 2021 16:29:57

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Name of Medication BUPIVACAINE 0.5%

Prophylaxis Yes ☐
No ☒

Indication VENTRAL HERNIA SURGERY

Dose per administration 30

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 (26)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	Intramuscular	<input 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 checked="" type="radio"/>
If route of administration is Other, specify		LOCAL INFILTRATION
Start date (dd MMM yyyy)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		24 MAR 2021
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 (27)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication MIDAZOLAM

Prophylaxis Yes ☐
No ☒

Indication SEDATION FOR VENTRAL
HERNIA SURGERY

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

AT 5 MINUTE OR 1 MINUTE
INTERVALS AS NEEDED FOR A
MAXIMUM DOSE OF 4 MG

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 30 Apr 2021 16:29:57

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	Transdermal	<input type="checkbox"/>
	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)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 MAR 2021	
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 (28)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication ENOXAPARIN

Prophylaxis Yes ☒
No ☐

Indication DVT PROPHYLAXIS

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 (28)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication NYSTATIN TOPICAL POWDER

Prophylaxis Yes ☒
No ☐

Indication ANTIFUNGAL PROPHYLAXIS OF
GROIN REGION

Dose per administration 100,000

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

If dose unit is Other, specify UNIT/GRAM

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 TWICE ON 25 MAR 2021 AND
ONCE ON 26 MAR 2021

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 MAR 2021
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 (30)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 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 (30)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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)	15 FEB 2021	
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)	2	
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 (31)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication POST-OP SOFT TISSUE
INFECTION

Dose per administration 500

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 (31)

Data signed: (b) (4) 30 Apr 2021 16:29:57

Generated On: 10 Jun 2021 07:59:48

	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)		12 APR 2021
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)		2
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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 11:38:53

Generated On: 10 Jun 2021 07:59:48

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) 22 Apr 2021 16:12:14

Generated On: 10 Jun 2021 07:59:48

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
24 MAR 2021	OPEN VENTRAL HERNIA REPAIR WITH REDUCTION OF STRANGULATED SMALL BOWEL	Adverse Event	
24 MAR 2021	CT ABDOMEN/PELVIS WITHOUT IV CONTRAST	Diagnostic	
24 MAR 2021	2019 NCORONAVIRUS, PCR (COVID-19) TEST	Diagnostic	
24 MAR 2021	PRE-OP BLOODWORK (CBC WITH DIFFERENTIAL, BMP, LIVER PROFILE, LIPASE, ABO/RH TYPE AND ANTIBODY SCREEN, PT/INR/PTT)	Adverse Event	
5 APR 2021	WOUND/ABSCESS/DRAINAGE CULTURE WITH GRAM STAIN	Diagnostic	
24 MAR 2021	PERITONEAL FLUID (SURGICAL) CULTURE AND GRAM STAIN	Diagnostic	
24 MAR 2021	SURGICAL SPECIMEN EXAM (PATHLOGY)	Diagnostic	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 07:59:48

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3522299

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:59:48

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 ☐

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

SAEID	USA-US131-2021-MRNA-1273-P301000014
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	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:59:48

SAEID	USA-US131-2021-MRNA-1273-P301000014
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	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	02/APR/2021 10:57
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

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:59:48

SAEID	USA-US131-2021-MRNA-1273-P301000014
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	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	21/APR/2021 09:09
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

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:59:48

SAEID	USA-US131-2021-MRNA-1273-P301000014
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	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	03/MAY/2021 07:46
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

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 07:59:48

SAEID	USA-US131-2021-MRNA-1273-P301000014
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	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	03/MAY/2021 15:07
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

Audit

US3522299 (Prod: Henry Ford Health System)

US3522299

Form: Participant Creation

Generated On: 10 Jun 2021 07:59:48

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 23:09:56
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
	(b) (4)	
User entered 'US3522299'	RWS_ENDPOINT	24 Aug 2020 11:39:27
	ENDPOINT (b) (4)	
	(b) (4)	

US3522299

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:05:30
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:48:45

US3522299

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:05:30
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 11:39:28

US3522299

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

[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 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:05:30
User entered 'Clinic (Clinic)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:48:45

US3522299

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered 'SCRN'	System	24 Aug 2020 11:48:45

US3522299

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:33
User entered (b) (6) 1962'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 11:39:29

US3522299

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:48

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:33
User entered '58'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:06

US3522299

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:48

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered 'YEARS'	System	24 Aug 2020 11:50:06

US3522299

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:48

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered '58'	System	24 Aug 2020 11:49:16

US3522299

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:48

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:33
User entered 'Female (F)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:06

US3522299

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:48

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:33
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:06

US3522299

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:48

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:33
User entered 'I'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:06

US3522299

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:48

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:33
User entered '0'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:06

US3522299

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:48

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:33
User entered '0'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:06

US3522299

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:48

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:33
User entered '0'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:06

US3522299

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:48

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:33
User entered '0'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:06

US3522299

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:33
User entered '0'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:06

US3522299

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:48

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:33
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:06

US3522299

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:48

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:33
User entered '0'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:06

US3522299

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:48

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:33
User entered '0'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:06

US3522299

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:48

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:40
User entered '24 Aug 2020'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:49:16

US3522299

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered 'Aug 2020'	System	24 Aug 2020 11:49:16

US3522299

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered '2020'	System	24 Aug 2020 11:49:16

US3522299

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:48

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:40
User entered 'Amendment 2 (2)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:49:16

US3522299

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:40
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:49:16

US3522299

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:48

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:40
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:49:16

US3522299

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:48

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:40
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:49:16

US3522299

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:48

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:40
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:49:16

US3522299

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:48

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:06:40
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 11:39:28

US3522299

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:48

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered 'I'	System	24 Aug 2020 11:49:32

US3522299

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:15:47
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:49:32

US3522299

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 07:59:48

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:15:51
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:01:31

US3522299

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Allergic asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 21:28:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 21:28:40
Data point term sent to Coder	System	24 Aug 2020 12:03:19
User entered 'asthma - mild allergy mediated'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:03:06

US3522299

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:03:06

US3522299

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered 'I'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:03:06

US3522299

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:03:06

US3522299

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:03:06

US3522299

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered '0'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:03:06

US3522299

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	24 Aug 2020 12:03:06

US3522299

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	24 Aug 2020 12:03:06

US3522299

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	24 Aug 2020 12:03:06

US3522299

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	24 Aug 2020 12:03:06

US3522299

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
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) (b) (4)	24 Aug 2020 15:04:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:04:32
Data point term sent to Coder	System	24 Aug 2020 12:04:20
User entered 'underactive thyroid'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:03:27

US3522299

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:03:27

US3522299

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered 'I'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:03:27

US3522299

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:03:27

US3522299

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:03:27

US3522299

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered '0'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:03:27

US3522299

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	24 Aug 2020 12:03:27

US3522299

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	24 Aug 2020 12:03:27

US3522299

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	24 Aug 2020 12:03:27

US3522299

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	24 Aug 2020 12:03:27

US3522299

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphatic disorder, LLT: Lymphatic disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 14:51:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 14:51:10
User closed query 'Per DM CLR: Please note that only 1 medical condition should be recorded per line. Review if these condition should be recorded separately ([1.] LYMPHATIC SYSTEM DAMAGE; [2.] BILATERAL LOWER EXTREMITY SWELLING). Review and update eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:30:40
Data point term sent to Coder	System	05 Oct 2020 19:04:39
Query 'Per DM CLR: Please note that only 1 medical condition should be recorded per line. Review if these condition should be recorded separately ([1.] LYMPHATIC SYSTEM DAMAGE; [2.] BILATERAL LOWER EXTREMITY SWELLING). Review and update eCRF as appropriate. Otherwise, clarify. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 19:04:22
Coding entries removed.	(b) (4), (b) (6)	05 Oct 2020 19:04:17
User entered 'LYMPHATIC SYSTEM DAMAGE' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 19:04:17

US3522299

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:48

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that only 1 medical condition should be recorded per line. Review if these condition should be recorded separately ([1.] LYMPHATIC SYSTEM DAMAGE; [2.] BILATERAL LOWER EXTREMITY SWELLING). Review and update eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:04:16
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Peripheral swelling, LLT: Swelling of legs - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 12:51:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 12:51:47
Data point term sent to Coder	System	24 Aug 2020 12:05:20
User entered 'lymphatic system damage causing bilateral lower extremity swelling'	Alandra White (b) (4)	24 Aug 2020 12:04:25

US3522299

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:04:25

US3522299

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered 'I'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:04:25

US3522299

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:04:25

US3522299

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:04:25

US3522299

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered '0'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:04:25

US3522299

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	24 Aug 2020 12:04:25

US3522299

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	24 Aug 2020 12:04:25

US3522299

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	24 Aug 2020 12:04:25

US3522299

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	24 Aug 2020 12:04:25

US3522299

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:43:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:43:42
Data point term sent to Coder	System	25 Aug 2020 15:42:22
User entered 'Obesity BMI > 40'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 15:41:35

US3522299

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 15:41:35

US3522299

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered 'l'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 15:41:35

US3522299

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 15:41:35

US3522299

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 15:41:35

US3522299

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered '0'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 15:41:35

US3522299

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	25 Aug 2020 15:41:35

US3522299

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	25 Aug 2020 15:41:35

US3522299

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	25 Aug 2020 15:41:35

US3522299

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	25 Aug 2020 15:41:35

US3522299

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:02:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:02:41
Data point term sent to Coder	System	04 Sep 2020 20:01:46
User entered 'Post Menopause'	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 20:01:14

US3522299

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Un-verified.	(b) (4)	
	Alandra White (b) (4)	15 Jan 2021 14:46:42
User entered 'UN Dec 2017' reason for change: Data	(b) (4)	
Entry Error	Alandra White (b) (4)	15 Jan 2021 14:46:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered 'un Dec 2016'	Sharon Mathys (b) (4)	04 Sep 2020 20:01:14
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered '0'	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 20:01:14

US3522299

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 20:01:14

US3522299

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 20:01:14

US3522299

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered '0'	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 20:01:14

US3522299

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered 'Dec 2017'	System	15 Jan 2021 14:46:42
User entered 'Dec 2016'	System	04 Sep 2020 20:01:14

US3522299

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered '2017'	System	15 Jan 2021 14:46:42
User entered '2016'	System	04 Sep 2020 20:01:14

US3522299

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	04 Sep 2020 20:01:14

US3522299

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	04 Sep 2020 20:01:14

US3522299

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Peripheral swelling, LLT: Swelling of legs - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 19:05:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 19:05:34
Data point term sent to Coder	System	05 Oct 2020 19:04:39
User entered 'BILATERAL LOWER EXTREMITY SWELLING'	(b) (4), (b) (6)	05 Oct 2020 19:04:38

US3522299

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 19:04:38

US3522299

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered 'l'	(b) (4), (b) (6)	05 Oct 2020 19:04:38

US3522299

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 19:04:38

US3522299

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 19:04:38

US3522299

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 19:04:38

US3522299

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	05 Oct 2020 19:04:38

US3522299

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	05 Oct 2020 19:04:38

US3522299

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	05 Oct 2020 19:04:38

US3522299

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	05 Oct 2020 19:04:38

US3522299

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
Query 'Per DM CLR: Please specify the location of ROSACEA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:27:21
User opened query 'Per DM CLR: Please specify the location of ROSACEA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:04:21
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Rosaceas, PT: Rosacea, LLT: Rosacea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:14:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:14:09
Data point term sent to Coder	System	06 Oct 2020 14:02:00
User entered 'Rosacea'	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:01:42

US3522299

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered empty.	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:01:42

US3522299

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered 'I'	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:01:42

US3522299

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:01:42

US3522299

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered empty.	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:01:42

US3522299

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered '0'	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:01:42

US3522299

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	06 Oct 2020 14:01:42

US3522299

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	06 Oct 2020 14:01:42

US3522299

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	06 Oct 2020 14:01:42

US3522299

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	06 Oct 2020 14:01:42

US3522299

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:23:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:23:16
Data point term sent to Coder	System	06 Oct 2020 14:21:54
User entered 'allergies- seasonal'	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:21:40

US3522299

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered empty.	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:21:40

US3522299

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered 'I'	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:21:40

US3522299

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:21:40

US3522299

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered empty.	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:21:40

US3522299

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:00
User entered '0'	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:21:40

US3522299

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	06 Oct 2020 14:21:40

US3522299

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	06 Oct 2020 14:21:40

US3522299

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	06 Oct 2020 14:21:40

US3522299

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered empty.	System	06 Oct 2020 14:21:40

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:05
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:00:15

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:05
User entered '24 Aug 2020'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:00:15

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:05
User entered '07:47'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:00:15

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered '24 Aug 2020 07:47'	System	24 Aug 2020 12:00:15

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:05
User entered '62' in	Alandra White (b) (4)	24 Aug 2020 12:00:15
DataPoint set to visible.	(b) (4) System	24 Aug 2020 11:49:32

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:05
User entered '247.9' lb	Alandra White (b) (4)	24 Aug 2020 12:00:15
DataPoint set to visible.	(b) (4) System	24 Aug 2020 11:49:32

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
Amendment Manager: User entered '45.43631'	System	17 Sep 2020 00:20:40
User entered '45.4'	System	24 Aug 2020 12:00:15
DataPoint set to visible.	System	24 Aug 2020 11:49:32

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered 'kg/m2'	System	24 Aug 2020 12:00:15
DataPoint set to visible.	System	24 Aug 2020 11:49:32

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:05
User entered missing code ND - Not Done.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:00:15

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:05
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 20:00:14
User entered 'Oral (Oral)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:00:15

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:05
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:00:15

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:05
User entered missing code ND - Not Done.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:00:15

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered 'bpm'	System	24 Aug 2020 12:00:15

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:05
User entered missing code ND - Not Done.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:00:15

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered 'breaths/min'	System	24 Aug 2020 12:00:15

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:05
User entered missing code ND - Not Done.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:00:15

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered 'mmHg'	System	24 Aug 2020 12:00:15

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:05
User entered missing code ND - Not Done.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:00:15

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User entered 'mmHg'	System	24 Aug 2020 12:00:15

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16

US3522299

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16

US3522299

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:22
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:55:30

US3522299

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:22
User entered '24 Aug 2020'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:55:30

US3522299

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:59:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:42
User entered '24 Aug 2020'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:51:49

US3522299

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:42
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:51:49

US3522299

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:59:48

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:42
User closed query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 00:32:25
Query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' answered with 'added' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 20:01:31
User opened query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 12:05:44
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:51:49

US3522299

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:42
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:51:49

US3522299

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:42
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:51:49

US3522299

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:59:48

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:42
User entered '0'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:51:49

US3522299

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:42
User entered 'un Dec 2016'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:51:49

US3522299

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:59:48

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:42
User entered '0'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:51:49

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

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 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

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 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

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 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

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 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

[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 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

[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 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

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 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

[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 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

[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 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

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 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

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 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered '0'	(b) (4) Alandra White (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered '0'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

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 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered '0'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

[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 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered '0'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

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 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered 'I'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered '0'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered '0'	(b) (4) Alandra White (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:19:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:53
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:50:55

US3522299

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:59
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:56:13

US3522299

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:59
User entered '24 Aug 2020'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:56:13

US3522299

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:18:59
User entered 'Clinic (Clinic)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:56:13

US3522299

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered 'VISIT1'	System	24 Aug 2020 11:56:13

US3522299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:06
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 11:49:34

US3522299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:06
User entered '144532'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 11:49:34

US3522299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:06
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 11:49:34

US3522299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:48

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)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:06
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:52:10

US3522299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:48

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)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:06
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:52:10

US3522299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:06
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:52:10

US3522299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:48

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:06
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:52:10

US3522299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:48

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:06
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:52:10

US3522299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:06
User entered 'No (N)'	Sharon Mathys (b) (4)	30 Oct 2020 17:59:07
Amendment Manager: DataPoint set to visible.	(b) (4)	
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 10:39:36
	System	19 Sep 2020 02:24:05

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:59:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered missing code ND - Not Done.	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:59:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered missing code ND - Not Done.	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:59:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered missing code ND - Not Done.	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:59:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered missing code ND - Not Done.	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User accepted default value 'Pre-Dose (PREDOSE)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered '24 Aug 2020'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered '07:47'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered '24 Aug 2020 07:47'	System	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered '97.3' F	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered 'Other (Other)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered 'temporal'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered '60'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered 'bpm'	System	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered '18'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered 'breaths/min'	System	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 18:55:50
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 15:43:12
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	24 Aug 2020 13:59:59
User entered '162'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered 'mmHg'	System	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered '85'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered 'mmHg'	System	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:59:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered missing code ND - Not Done.	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:59:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered missing code ND - Not Done.	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User accepted default value 'Post-Dose (POSTDOSE)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered '24 Aug 2020'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered '09:45'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered '24 Aug 2020 09:45'	System	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered '97.4' F	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered 'Other (Other)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered 'temporal'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered '60'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered 'bpm'	System	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered '18'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered 'breaths/min'	System	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 18:57:08
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 15:43:24
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	24 Aug 2020 13:59:59
User entered '170'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered 'mmHg'	System	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:45
User entered '95'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered 'mmHg'	System	24 Aug 2020 13:59:59

US3522299

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:53
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:56:02

US3522299

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:19:53
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 11:56:02

US3522299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:04
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:28:27

US3522299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:04
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:28:27

US3522299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

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)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:04
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:28:27

US3522299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 13:28:27

US3522299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:04
User entered '24 Aug 2020'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:28:27

US3522299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:04
User entered '09:15'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:28:27

US3522299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered '24 Aug 2020 09:15'	System	24 Aug 2020 13:28:27

US3522299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:04
User entered 'Left Arm (LEFT ARM)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:28:27

US3522299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 20:20:04
User entered 'ONCE'	System	24 Aug 2020 13:28:27

US3522299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 13:28:27

US3522299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:08
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:18:28

US3522299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:08
User entered '24 Aug 2020'	Alandra White (b) (4) (b) (4)	24 Aug 2020 13:18:28

US3522299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:08
User entered '09:10' reason for change: Data Entry Error	Alandra White (b) (4)	24 Aug 2020 13:28:04
User entered '09:15'	(b) (4) Alandra White (b) (4) (b) (4)	24 Aug 2020 13:18:28

US3522299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered '24 Aug 2020 09:10'	System	24 Aug 2020 13:28:04
User entered '24 Aug 2020 09:15'	System	24 Aug 2020 13:18:28

US3522299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:59:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:20
User entered '24 Aug 2020'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:16:20

US3522299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:16:20

US3522299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:20
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:16:20

US3522299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:20
User entered '08:05'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:16:20

US3522299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered '24 Aug 2020 08:05'	System	24 Aug 2020 12:16:20

US3522299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:16:20

US3522299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:20
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:16:20

US3522299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:20
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:16:20

US3522299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered empty.	System	24 Aug 2020 12:16:20

US3522299

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:26
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	31 Aug 2020 13:32:03

US3522299

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered '1'	System	31 Aug 2020 13:32:03

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T09:49:35', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a7bfd562-ea14-41b4-a6bc-8eac442e8f63'	System	24 Aug 2020 14:01:57
User entered 'Yes (Y)'	System	24 Aug 2020 14:01:57

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T09:49:43', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a7bfd562-ea14-41b4-a6bc-8eac442e8f63'	System	24 Aug 2020 14:01:57
User entered '97.4'	System	24 Aug 2020 14:01:57

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T10:01:48', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a7bfd562-ea14-41b4-a6bc-8eac442e8f63'	System	24 Aug 2020 14:01:57
User entered 'No (N)'	System	24 Aug 2020 14:01:57

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T10:01:54', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a7bfd562-ea14-41b4-a6bc-8eac442e8f63'	System	24 Aug 2020 14:01:57
User entered '24 Aug 2020 10:01'	System	24 Aug 2020 14:01:57

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '24 Aug 2020 09:35'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '24 Aug 2020 12:05'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:56:31', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a20d7a1a-6780-4139-abfb-38abd3e99884'	System	24 Aug 2020 21:57:15
User entered 'Yes (Y)'	System	24 Aug 2020 21:57:15

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:56:39', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a20d7a1a-6780-4139-abfb-38abd3e99884'	System	24 Aug 2020 21:57:15
User entered '98.5'	System	24 Aug 2020 21:57:15

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:56:48', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a20d7a1a-6780-4139-abfb-38abd3e99884'	System	24 Aug 2020 21:57:15
User entered 'Yes (Y)'	System	24 Aug 2020 21:57:15

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient was contact, took Tylenol, refer to con meds line 8' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 08:20:06
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 18:41:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:56:59', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a20d7a1a-6780-4139-abfb-38abd3e99884'	System	24 Aug 2020 21:57:15
User entered '1'	System	24 Aug 2020 21:57:15

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:56:59', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a20d7a1a-6780-4139-abfb-38abd3e99884' User entered '0'	System	24 Aug 2020 21:57:15
	System	24 Aug 2020 21:57:15

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:57:09', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a20d7a1a-6780-4139-abfb-38abd3e99884'	System	24 Aug 2020 21:57:15
User entered '24 Aug 2020 17:57'	System	24 Aug 2020 21:57:15

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '24 Aug 2020 13:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 2'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-25T17:57:31', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f6ea4da7-5553-4b5d-a9f7-1c0e9db0099f'	System	25 Aug 2020 21:57:53
User entered 'Yes (Y)'	System	25 Aug 2020 21:57:53

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-25T17:57:39', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f6ea4da7-5553-4b5d-a9f7-1c0e9db0099f' User entered '97.6'	System	25 Aug 2020 21:57:53
	System	25 Aug 2020 21:57:53

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-25T17:57:43', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f6ea4da7-5553-4b5d-a9f7-1c0e9db0099f'	System	25 Aug 2020 21:57:53
User entered 'No (N)'	System	25 Aug 2020 21:57:53

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-25T17:57:49', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f6ea4da7-5553-4b5d-a9f7-1c0e9db0099f'	System	25 Aug 2020 21:57:53
User entered '25 Aug 2020 17:57'	System	25 Aug 2020 21:57:53

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 3'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-26T18:04:06', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd329249a-e7e3-401e-ad2a-7a170c7a6656'	System	26 Aug 2020 22:04:23
User entered 'Yes (Y)'	System	26 Aug 2020 22:04:23

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-26T18:04:12', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd329249a-e7e3-401e-ad2a-7a170c7a6656'	System	26 Aug 2020 22:04:23
User entered '98.1'	System	26 Aug 2020 22:04:23

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-26T18:04:16', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd329249a-e7e3-401e-ad2a-7a170c7a6656'	System	26 Aug 2020 22:04:23
User entered 'No (N)'	System	26 Aug 2020 22:04:23

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-26T18:04:21', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd329249a-e7e3-401e-ad2a-7a170c7a6656'	System	26 Aug 2020 22:04:23
User entered '26 Aug 2020 18:04'	System	26 Aug 2020 22:04:23

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 4'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-27T17:59:59', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '56199c88-f1ff-4999-8aed-7238cdc2286b'	System	27 Aug 2020 22:00:29
User entered 'Yes (Y)'	System	27 Aug 2020 22:00:29

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-27T18:00:08', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '56199c88-f1ff-4999-8aed-7238cdc2286b' User entered '98.2'	System	27 Aug 2020 22:00:29
	System	27 Aug 2020 22:00:29

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-27T18:00:12', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '56199c88-f1ff-4999-8aed-7238cdc2286b'	System	27 Aug 2020 22:00:29
User entered 'No (N)'	System	27 Aug 2020 22:00:29

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-27T18:00:17', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '56199c88-f1ff-4999-8aed-7238cdc2286b'	System	27 Aug 2020 22:00:29
User entered '27 Aug 2020 18:00'	System	27 Aug 2020 22:00:29

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 5'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-28T17:59:11', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'dcf5a7aa-3618-4c4b-b9bc-d49454c3f8a1'	System	28 Aug 2020 21:59:29
User entered 'Yes (Y)'	System	28 Aug 2020 21:59:29

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-28T17:59:18', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'dcf5a7aa-3618-4c4b-b9bc-d49454c3f8a1'	System	28 Aug 2020 21:59:29
User entered '98.0'	System	28 Aug 2020 21:59:29

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-28T17:59:22', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'dcf5a7aa-3618-4c4b-b9bc-d49454c3f8a1'	System	28 Aug 2020 21:59:29
User entered 'No (N)'	System	28 Aug 2020 21:59:29

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-28T17:59:26', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'dcf5a7aa-3618-4c4b-b9bc-d49454c3f8a1'	System	28 Aug 2020 21:59:29
User entered '28 Aug 2020 17:59'	System	28 Aug 2020 21:59:29

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 6'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-29T17:56:18', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '6871dd53-688e-40c6-8b5f-eb395407d50a'	System	29 Aug 2020 21:56:47
User entered 'Yes (Y)'	System	29 Aug 2020 21:56:47

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-29T17:56:26', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '6871dd53-688e-40c6-8b5f-eb395407d50a' User entered '98.7'	System	29 Aug 2020 21:56:47
	System	29 Aug 2020 21:56:47

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-29T17:56:30', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '6871dd53-688e-40c6-8b5f-eb395407d50a'	System	29 Aug 2020 21:56:47
User entered 'No (N)'	System	29 Aug 2020 21:56:47

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-29T17:56:33', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '6871dd53-688e-40c6-8b5f-eb395407d50a'	System	29 Aug 2020 21:56:47
User entered '29 Aug 2020 17:56'	System	29 Aug 2020 21:56:47

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 7'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-30T18:07:04', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8e5b5b31-8787-438d-88da-389ecadb56fc'	System	30 Aug 2020 22:07:28
User entered 'Yes (Y)'	System	30 Aug 2020 22:07:28

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-30T18:07:10', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8e5b5b31-8787-438d-88da-389ecadb56fc'	System	30 Aug 2020 22:07:28
User entered '98.4'	System	30 Aug 2020 22:07:28

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-30T18:07:22', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8e5b5b31-8787-438d-88da-389ecadb56fc'	System	30 Aug 2020 22:07:28
User entered 'No (N)'	System	30 Aug 2020 22:07:28

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-30T18:07:24', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8e5b5b31-8787-438d-88da-389ecadb56fc'	System	30 Aug 2020 22:07:28
User entered '30 Aug 2020 18:07'	System	30 Aug 2020 22:07:28

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T09:59:12', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0cc5c9a1-1e47-4fbe-8e89-aeee1b5398f1'	System	24 Aug 2020 14:00:19
User entered 'None (1)'	System	24 Aug 2020 14:00:19

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T09:59:28', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0cc5c9a1-1e47-4fbe-8e89-aeec1b5398f1'	System	24 Aug 2020 14:00:19
User entered 'No (N)'	System	24 Aug 2020 14:00:19

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T09:59:34', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0cc5c9a1-1e47-4fbe-8e89-aece1b5398f1'	System	24 Aug 2020 14:00:19
User entered 'No (N)'	System	24 Aug 2020 14:00:19

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T09:59:45', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0cc5c9a1-1e47-4fbe-8e89-aeee1b5398f1'	System	24 Aug 2020 14:00:19
User entered 'None (1)'	System	24 Aug 2020 14:00:19

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T10:00:16', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0cc5c9a1-1e47-4fbe-8e89-aeee1b5398f1'	System	24 Aug 2020 14:00:19
User entered '24 Aug 2020 10:00'	System	24 Aug 2020 14:00:19

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '24 Aug 2020 09:35'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '24 Aug 2020 12:05'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:57:17', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8ac6aa08-9485-40bd-81bc-6a9ac0dd40a9'	System	24 Aug 2020 21:57:43
User entered 'None (1)'	System	24 Aug 2020 21:57:43

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:57:22', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8ac6aa08-9485-40bd-81bc-6a9ac0dd40a9'	System	24 Aug 2020 21:57:43
User entered 'No (N)'	System	24 Aug 2020 21:57:43

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:57:27', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8ac6aa08-9485-40bd-81bc-6a9ac0dd40a9'	System	24 Aug 2020 21:57:43
User entered 'No (N)'	System	24 Aug 2020 21:57:43

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:57:32', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8ac6aa08-9485-40bd-81bc-6a9ac0dd40a9'	System	24 Aug 2020 21:57:43
User entered 'None (1)'	System	24 Aug 2020 21:57:43

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:57:40', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8ac6aa08-9485-40bd-81bc-6a9ac0dd40a9'	System	24 Aug 2020 21:57:43
User entered '24 Aug 2020 17:57'	System	24 Aug 2020 21:57:43

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '24 Aug 2020 13:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 2'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-25T17:57:57', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'e97b95e4-4bfd-447d-9d6a-8e604e24f88d'	System	25 Aug 2020 21:58:21
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 21:58:21

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-25T17:58:01', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'e97b95e4-4bfd-447d-9d6a-8e604e24f88d'	System	25 Aug 2020 21:58:21
User entered 'No (N)'	System	25 Aug 2020 21:58:21

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-25T17:58:05', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'e97b95e4-4bfd-447d-9d6a-8e604e24f88d'	System	25 Aug 2020 21:58:21
User entered 'No (N)'	System	25 Aug 2020 21:58:21

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-25T17:58:12', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'e97b95e4-4bfd-447d-9d6a-8e604e24f88d'	System	25 Aug 2020 21:58:21
User entered 'None (1)'	System	25 Aug 2020 21:58:21

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-25T17:58:16', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'e97b95e4-4bfd-447d-9d6a-8e604e24f88d'	System	25 Aug 2020 21:58:21
User entered '25 Aug 2020 17:58'	System	25 Aug 2020 21:58:21

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 3'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-26T18:04:27', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd363d43b-8c85-448d-98fa-591dcabde991'	System	26 Aug 2020 22:04:48
User entered 'None (1)'	System	26 Aug 2020 22:04:48

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-26T18:04:31', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd363d43b-8c85-448d-98fa-591dcabde991'	System	26 Aug 2020 22:04:48
User entered 'No (N)'	System	26 Aug 2020 22:04:48

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-26T18:04:35', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd363d43b-8c85-448d-98fa-591dcabde991'	System	26 Aug 2020 22:04:48
User entered 'No (N)'	System	26 Aug 2020 22:04:48

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-26T18:04:40', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd363d43b-8c85-448d-98fa-591dcabde991'	System	26 Aug 2020 22:04:48
User entered 'None (1)'	System	26 Aug 2020 22:04:48

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-26T18:04:43', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd363d43b-8c85-448d-98fa-591dcabde991'	System	26 Aug 2020 22:04:48
User entered '26 Aug 2020 18:04'	System	26 Aug 2020 22:04:48

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 4'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-27T18:00:23', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '3f96f761-9e36-4a5e-8322-8a75ae9d1d81'	System	27 Aug 2020 22:00:40
User entered 'None (1)'	System	27 Aug 2020 22:00:40

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-27T18:00:27', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '3f96f761-9e36-4a5e-8322-8a75ae9d1d81'	System	27 Aug 2020 22:00:40
User entered 'No (N)'	System	27 Aug 2020 22:00:40

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-27T18:00:30', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '3f96f761-9e36-4a5e-8322-8a75ae9d1d81'	System	27 Aug 2020 22:00:40
User entered 'No (N)'	System	27 Aug 2020 22:00:40

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-27T18:00:35', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '3f96f761-9e36-4a5e-8322-8a75ae9d1d81'	System	27 Aug 2020 22:00:40
User entered 'None (1)'	System	27 Aug 2020 22:00:40

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-27T18:00:38', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '3f96f761-9e36-4a5e-8322-8a75ae9d1d81'	System	27 Aug 2020 22:00:40
User entered '27 Aug 2020 18:00'	System	27 Aug 2020 22:00:40

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 5'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-28T17:59:31', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '4341fa79-7dc9-4488-b454-35056a97f750'	System	28 Aug 2020 21:59:53
User entered 'None (1)'	System	28 Aug 2020 21:59:53

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-28T17:59:36', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '4341fa79-7dc9-4488-b454-35056a97f750'	System	28 Aug 2020 21:59:53
User entered 'No (N)'	System	28 Aug 2020 21:59:53

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-28T17:59:39', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '4341fa79-7dc9-4488-b454-35056a97f750'	System	28 Aug 2020 21:59:53
User entered 'No (N)'	System	28 Aug 2020 21:59:53

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-28T17:59:46', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '4341fa79-7dc9-4488-b454-35056a97f750'	System	28 Aug 2020 21:59:53
User entered 'None (1)'	System	28 Aug 2020 21:59:53

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-28T17:59:51', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '4341fa79-7dc9-4488-b454-35056a97f750'	System	28 Aug 2020 21:59:53
User entered '28 Aug 2020 17:59'	System	28 Aug 2020 21:59:53

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 6'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-29T17:56:39', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'b4ca2a89-187b-4890-bc96-4c6413a6c0f3'	System	29 Aug 2020 21:57:01
User entered 'None (1)'	System	29 Aug 2020 21:57:01

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-29T17:56:42', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'b4ca2a89-187b-4890-bc96-4c6413a6c0f3'	System	29 Aug 2020 21:57:01
User entered 'No (N)'	System	29 Aug 2020 21:57:01

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-29T17:56:48', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'b4ca2a89-187b-4890-bc96-4c6413a6c0f3'	System	29 Aug 2020 21:57:01
User entered 'No (N)'	System	29 Aug 2020 21:57:01

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-29T17:56:52', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'b4ca2a89-187b-4890-bc96-4c6413a6c0f3'	System	29 Aug 2020 21:57:01
User entered 'None (1)'	System	29 Aug 2020 21:57:01

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-29T17:56:56', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'b4ca2a89-187b-4890-bc96-4c6413a6c0f3'	System	29 Aug 2020 21:57:01
User entered '29 Aug 2020 17:56'	System	29 Aug 2020 21:57:01

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 7'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-30T18:07:30', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8e5c3aed-c081-415c-baab-686deec08ff9'	System	30 Aug 2020 22:07:51
User entered 'None (1)'	System	30 Aug 2020 22:07:51

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-30T18:07:33', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8e5c3aed-c081-415c-baab-686deec08ff9'	System	30 Aug 2020 22:07:51
User entered 'No (N)'	System	30 Aug 2020 22:07:51

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-30T18:07:37', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8e5c3aed-c081-415c-baab-686deec08ff9'	System	30 Aug 2020 22:07:51
User entered 'No (N)'	System	30 Aug 2020 22:07:51

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-30T18:07:43', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8e5c3aed-c081-415c-baab-686deec08ff9'	System	30 Aug 2020 22:07:51
User entered 'None (1)'	System	30 Aug 2020 22:07:51

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-30T18:07:47', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8e5c3aed-c081-415c-baab-686deec08ff9'	System	30 Aug 2020 22:07:51
User entered '30 Aug 2020 18:07'	System	30 Aug 2020 22:07:51

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T10:00:24', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '5edb4e75-eed8-4b5f-b2d0-da198d6948ce'	System	24 Aug 2020 14:01:01
User entered 'None (0)'	System	24 Aug 2020 14:01:01

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T10:00:28', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '5edb4e75-eed8-4b5f-b2d0-da198d6948ce'	System	24 Aug 2020 14:01:01
User entered 'None (0)'	System	24 Aug 2020 14:01:01

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T10:00:40', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '5edb4e75-eed8-4b5f-b2d0-da198d6948ce'	System	24 Aug 2020 14:01:01
User entered 'None (0)'	System	24 Aug 2020 14:01:01

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T10:00:43', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '5edb4e75-eed8-4b5f-b2d0-da198d6948ce' User entered 'None (0)'	System	24 Aug 2020 14:01:01
	System	24 Aug 2020 14:01:01

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T10:00:46', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '5edb4e75-eed8-4b5f-b2d0-da198d6948ce'	System	24 Aug 2020 14:01:01
User entered 'None (0)'	System	24 Aug 2020 14:01:01

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T10:00:49', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '5edb4e75-eed8-4b5f-b2d0-da198d6948ce' User entered 'None (0)'	System	24 Aug 2020 14:01:01
	System	24 Aug 2020 14:01:01

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

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)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T10:00:52', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '5edb4e75-eed8-4b5f-b2d0-da198d6948ce'	System	24 Aug 2020 14:01:01
User entered 'No (N)'	System	24 Aug 2020 14:01:01

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T10:00:57', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '5edb4e75-eed8-4b5f-b2d0-da198d6948ce'	System	24 Aug 2020 14:01:01
User entered '24 Aug 2020 10:00'	System	24 Aug 2020 14:01:01

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '24 Aug 2020 09:35'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '24 Aug 2020 12:05'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:57:59', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '04d46c7d-db97-4dcb-a80e-c609a35a16e6'	System	24 Aug 2020 21:58:37
User entered 'No interference with activity (1)'	System	24 Aug 2020 21:58:37

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:58:03', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '04d46c7d-db97-4dcb-a80e-c609a35a16e6'	System	24 Aug 2020 21:58:37
User entered 'None (0)'	System	24 Aug 2020 21:58:37

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:58:07', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '04d46c7d-db97-4dcb-a80e-c609a35a16e6' User entered 'None (0)'	System	24 Aug 2020 21:58:37
	System	24 Aug 2020 21:58:37

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:58:10', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '04d46c7d-db97-4dcb-a80e-c609a35a16e6'	System	24 Aug 2020 21:58:37
User entered 'None (0)'	System	24 Aug 2020 21:58:37

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:58:15', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '04d46c7d-db97-4dcb-a80e-c609a35a16e6'	System	24 Aug 2020 21:58:37
User entered 'None (0)'	System	24 Aug 2020 21:58:37

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:58:22', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '04d46c7d-db97-4dcb-a80e-c609a35a16e6'	System	24 Aug 2020 21:58:37
User entered 'No interference with activity (1)'	System	24 Aug 2020 21:58:37

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:58:27', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '04d46c7d-db97-4dcb-a80e-c609a35a16e6'	System	24 Aug 2020 21:58:37
User entered 'No (N)'	System	24 Aug 2020 21:58:37

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-24T17:58:31', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '04d46c7d-db97-4dcb-a80e-c609a35a16e6'	System	24 Aug 2020 21:58:37
User entered '24 Aug 2020 17:58'	System	24 Aug 2020 21:58:37

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '24 Aug 2020 13:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 2'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-25T17:58:21', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0d366a30-ecfd-4ba2-bdde-c5bc0d6fa4f3'	System	25 Aug 2020 21:58:50
User entered 'None (0)'	System	25 Aug 2020 21:58:50

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-25T17:58:24', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0d366a30-ecfd-4ba2-bdde-c5bc0d6fa4f3'	System	25 Aug 2020 21:58:50
User entered 'None (0)'	System	25 Aug 2020 21:58:50

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-25T17:58:27', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0d366a30-ecfd-4ba2-bdde-c5bc0d6fa4f3'	System	25 Aug 2020 21:58:50
User entered 'None (0)'	System	25 Aug 2020 21:58:50

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-25T17:58:30', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0d366a30-ecfd-4ba2-bdde-c5bc0d6fa4f3'	System	25 Aug 2020 21:58:50
User entered 'None (0)'	System	25 Aug 2020 21:58:50

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-25T17:58:33', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0d366a30-ecfd-4ba2-bdde-c5bc0d6fa4f3'	System	25 Aug 2020 21:58:50
User entered 'None (0)'	System	25 Aug 2020 21:58:50

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-25T17:58:36', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0d366a30-ecfd-4ba2-bdde-c5bc0d6fa4f3'	System	25 Aug 2020 21:58:50
User entered 'None (0)'	System	25 Aug 2020 21:58:50

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

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)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-25T17:58:42', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0d366a30-ecfd-4ba2-bdde-c5bc0d6fa4f3'	System	25 Aug 2020 21:58:50
User entered 'No (N)'	System	25 Aug 2020 21:58:50

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-25T17:58:45', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0d366a30-ecfd-4ba2-bdde-c5bc0d6fa4f3'	System	25 Aug 2020 21:58:50
User entered '25 Aug 2020 17:58'	System	25 Aug 2020 21:58:50

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 3'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-26T18:04:49', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '1369b672-9667-4546-85ae-73c4c5bdfbba'	System	26 Aug 2020 22:05:17
User entered 'None (0)'	System	26 Aug 2020 22:05:17

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-26T18:04:51', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '1369b672-9667-4546-85ae-73c4c5bdfbba'	System	26 Aug 2020 22:05:17
User entered 'None (0)'	System	26 Aug 2020 22:05:17

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-26T18:04:55', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '1369b672-9667-4546-85ae-73c4c5bdfbba'	System	26 Aug 2020 22:05:17
User entered 'None (0)'	System	26 Aug 2020 22:05:17

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-26T18:04:58', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '1369b672-9667-4546-85ae-73c4c5bdfbba'	System	26 Aug 2020 22:05:17
User entered 'None (0)'	System	26 Aug 2020 22:05:17

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-26T18:05:01', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '1369b672-9667-4546-85ae-73c4c5bdfbba'	System	26 Aug 2020 22:05:17
User entered 'None (0)'	System	26 Aug 2020 22:05:17

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-26T18:05:04', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '1369b672-9667-4546-85ae-73c4c5bdfbba'	System	26 Aug 2020 22:05:17
User entered 'None (0)'	System	26 Aug 2020 22:05:17

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

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)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-26T18:05:10', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '1369b672-9667-4546-85ae-73c4c5bdfbba'	System	26 Aug 2020 22:05:17
User entered 'No (N)'	System	26 Aug 2020 22:05:17

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-26T18:05:13', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '1369b672-9667-4546-85ae-73c4c5bdfbba'	System	26 Aug 2020 22:05:17
User entered '26 Aug 2020 18:05'	System	26 Aug 2020 22:05:17

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 4'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-27T18:00:43', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '50f125a5-d0c6-4278-9420-b8f7d9c77da7'	System	27 Aug 2020 22:01:09
User entered 'None (0)'	System	27 Aug 2020 22:01:09

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-27T18:00:46', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '50f125a5-d0c6-4278-9420-b8f7d9c77da7'	System	27 Aug 2020 22:01:09
User entered 'None (0)'	System	27 Aug 2020 22:01:09

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-27T18:00:49', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '50f125a5-d0c6-4278-9420-b8f7d9c77da7'	System	27 Aug 2020 22:01:09
User entered 'None (0)'	System	27 Aug 2020 22:01:09

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-27T18:00:51', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '50f125a5-d0c6-4278-9420-b8f7d9c77da7'	System	27 Aug 2020 22:01:09
User entered 'None (0)'	System	27 Aug 2020 22:01:09

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-27T18:00:54', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '50f125a5-d0c6-4278-9420-b8f7d9c77da7'	System	27 Aug 2020 22:01:09
User entered 'None (0)'	System	27 Aug 2020 22:01:09

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-27T18:00:57', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '50f125a5-d0c6-4278-9420-b8f7d9c77da7'	System	27 Aug 2020 22:01:09
User entered 'None (0)'	System	27 Aug 2020 22:01:09

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

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)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-27T18:01:01', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '50f125a5-d0c6-4278-9420-b8f7d9c77da7'	System	27 Aug 2020 22:01:09
User entered 'No (N)'	System	27 Aug 2020 22:01:09

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-27T18:01:04', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '50f125a5-d0c6-4278-9420-b8f7d9c77da7'	System	27 Aug 2020 22:01:09
User entered '27 Aug 2020 18:01'	System	27 Aug 2020 22:01:09

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 5'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-28T17:59:55', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '75d73a9b-bab6-4449-aef7-fb026616391d'	System	28 Aug 2020 22:00:16
User entered 'None (0)'	System	28 Aug 2020 22:00:16

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-28T17:59:58', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '75d73a9b-bab6-4449-aef7-fb026616391d'	System	28 Aug 2020 22:00:16
User entered 'None (0)'	System	28 Aug 2020 22:00:16

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-28T18:00:00', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '75d73a9b-bab6-4449-aef7-fb026616391d'	System	28 Aug 2020 22:00:16
User entered 'None (0)'	System	28 Aug 2020 22:00:16

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-28T18:00:02', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '75d73a9b-bab6-4449-aef7-fb026616391d'	System	28 Aug 2020 22:00:16
User entered 'None (0)'	System	28 Aug 2020 22:00:16

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-28T18:00:04', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '75d73a9b-bab6-4449-aef7-fb026616391d'	System	28 Aug 2020 22:00:16
User entered 'None (0)'	System	28 Aug 2020 22:00:16

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-28T18:00:06', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '75d73a9b-bab6-4449-aef7-fb026616391d'	System	28 Aug 2020 22:00:16
User entered 'None (0)'	System	28 Aug 2020 22:00:16

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

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)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-28T18:00:10', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '75d73a9b-bab6-4449-aef7-fb026616391d'	System	28 Aug 2020 22:00:16
User entered 'No (N)'	System	28 Aug 2020 22:00:16

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-28T18:00:13', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '75d73a9b-bab6-4449-aef7-fb026616391d'	System	28 Aug 2020 22:00:16
User entered '28 Aug 2020 18:00'	System	28 Aug 2020 22:00:16

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 6'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-29T17:57:05', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '9bef83dd-c742-4b6f-991d-4f6b866543f1'	System	29 Aug 2020 21:57:32
User entered 'None (0)'	System	29 Aug 2020 21:57:32

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-29T17:57:08', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '9bef83dd-c742-4b6f-991d-4f6b866543f1'	System	29 Aug 2020 21:57:32
User entered 'None (0)'	System	29 Aug 2020 21:57:32

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-29T17:57:10', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '9bef83dd-c742-4b6f-991d-4f6b866543f1' User entered 'None (0)'	System	29 Aug 2020 21:57:32
	System	29 Aug 2020 21:57:32

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-29T17:57:13', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '9bef83dd-c742-4b6f-991d-4f6b866543f1'	System	29 Aug 2020 21:57:32
User entered 'None (0)'	System	29 Aug 2020 21:57:32

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-29T17:57:16', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '9bef83dd-c742-4b6f-991d-4f6b866543f1'	System	29 Aug 2020 21:57:32
User entered 'None (0)'	System	29 Aug 2020 21:57:32

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-29T17:57:19', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '9bef83dd-c742-4b6f-991d-4f6b866543f1'	System	29 Aug 2020 21:57:32
User entered 'None (0)'	System	29 Aug 2020 21:57:32

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

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)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-29T17:57:25', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '9bef83dd-c742-4b6f-991d-4f6b866543f1'	System	29 Aug 2020 21:57:32
User entered 'No (N)'	System	29 Aug 2020 21:57:32

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-29T17:57:28', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '9bef83dd-c742-4b6f-991d-4f6b866543f1'	System	29 Aug 2020 21:57:32
User entered '29 Aug 2020 17:57'	System	29 Aug 2020 21:57:32

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 7'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-30T18:07:52', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '3cacf311-372b-4593-b95e-9e98c969b5c6'	System	30 Aug 2020 22:08:16
User entered 'None (0)'	System	30 Aug 2020 22:08:16

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-30T18:07:55', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '3cacf311-372b-4593-b95e-9e98c969b5c6'	System	30 Aug 2020 22:08:16
User entered 'None (0)'	System	30 Aug 2020 22:08:16

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-30T18:07:57', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '3cacf311-372b-4593-b95e-9e98c969b5c6'	System	30 Aug 2020 22:08:16
User entered 'None (0)'	System	30 Aug 2020 22:08:16

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-30T18:07:59', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '3cacf311-372b-4593-b95e-9e98c969b5c6'	System	30 Aug 2020 22:08:16
User entered 'None (0)'	System	30 Aug 2020 22:08:16

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-30T18:08:02', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '3cacf311-372b-4593-b95e-9e98c969b5c6'	System	30 Aug 2020 22:08:16
User entered 'None (0)'	System	30 Aug 2020 22:08:16

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-30T18:08:05', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '3cacf311-372b-4593-b95e-9e98c969b5c6'	System	30 Aug 2020 22:08:16
User entered 'None (0)'	System	30 Aug 2020 22:08:16

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

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)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-30T18:08:09', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '3cacf311-372b-4593-b95e-9e98c969b5c6'	System	30 Aug 2020 22:08:16
User entered 'No (N)'	System	30 Aug 2020 22:08:16

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-08-30T18:08:11', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '3cacf311-372b-4593-b95e-9e98c969b5c6'	System	30 Aug 2020 22:08:16
User entered '30 Aug 2020 18:08'	System	30 Aug 2020 22:08:16

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 13:28:27

US3522299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:43
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	31 Aug 2020 13:34:14

US3522299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:43
User entered '31 Aug 2020'	Alayna Wilder (b) (4) (b) (4)	31 Aug 2020 13:34:14

US3522299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:43
User entered 'Contact Made (CONTACT MADE)'	Alayna Wilder (b) (4) (b) (4)	31 Aug 2020 13:34:14

US3522299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:43
User entered 'Reported HA and chills which is normal per baseline, however pt reported symptoms were exacerbated after injection. Symptoms have since resolved. No COVID contact.'	Alayna Wilder (b) (4) (b) (4)	31 Aug 2020 13:34:14

US3522299

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 13:58:46

US3522299

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered 'I'	System	08 Sep 2020 13:58:46

US3522299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 13:59:18

US3522299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:55
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 13:59:18

US3522299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Sep 2020 13:59:18

US3522299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:55
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	(b) (4), (b) (6)	08 Sep 2020 13:59:18

US3522299

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:20:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 13:59:23

US3522299

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:55:20
User entered 'I'	System	08 Sep 2020 13:59:23

US3522299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:57:18
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:15:16

US3522299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:57:18
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:15:16

US3522299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:57:18
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:15:16

US3522299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:57:18
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered "'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'"	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:15:16

US3522299

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:57:21
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:15:21

US3522299

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:09
User entered 'I'	System	14 Sep 2020 13:15:21

US3522299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:57:57
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 12:36:29

US3522299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:57:57
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 12:36:29

US3522299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

[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 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:57:57
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 12:36:29

US3522299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'VISIT2'	System	21 Sep 2020 12:36:29

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Sep 2020 12:37:11

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 12:37:11

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 12:37:11

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User closed query 'Per source review time is 08.27. Please review and update.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:55:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:55:47
Query 'Per source review time is 08.27. Please review and update.' answered with 'updated' (Site from CRA).	Sharon Mathys (b) (4)	04 Mar 2021 18:38:42
Signature has been broken.	Sharon Mathys (b) (4)	04 Mar 2021 18:38:37
User entered '08:27' reason for change: Data Entry Error	Sharon Mathys (b) (4)	04 Mar 2021 18:38:37
User opened query 'Per source review time is 08.27. Please review and update.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:00:50
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 16:00:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '08:36'	(b) (4), (b) (6)	21 Sep 2020 12:37:11

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered '21 Sep 2020 08:27'	System	04 Mar 2021 18:38:37
User entered '21 Sep 2020 08:36'	System	21 Sep 2020 12:37:11

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '97.8' F	(b) (4), (b) (6)	21 Sep 2020 12:37:11

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 12:37:11

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 12:37:11

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '67'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 12:37:11

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'bpm'	System	21 Sep 2020 12:37:11

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '18'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 12:37:11

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'breaths/min'	System	21 Sep 2020 12:37:11

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '179'	(b) (4), (b) (6)	21 Sep 2020 12:37:11

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'mmHg'	System	21 Sep 2020 12:37:11

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '93'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 12:37:11

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'mmHg'	System	21 Sep 2020 12:37:11

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Sep 2020 13:21:22

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:02:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:21:22

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:02:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:21:22

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:02:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '09:20'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:21:22

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered '21 Sep 2020 09:20'	System	21 Sep 2020 13:21:22

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:02:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '98.3' F	(b) (4), (b) (6)	21 Sep 2020 13:21:22

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:02:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:21:22

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:02:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:21:22

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:02:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '62'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:21:22

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'bpm'	System	21 Sep 2020 13:21:22

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:02:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '16'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:21:22

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'breaths/min'	System	21 Sep 2020 13:21:22

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:02:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '169'	(b) (4), (b) (6)	21 Sep 2020 13:21:22

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'mmHg'	System	21 Sep 2020 13:21:22

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:02:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '84'	(b) (4), (b) (6)	21 Sep 2020 13:21:22

US3522299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'mmHg'	System	21 Sep 2020 13:21:22

US3522299

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:02:30
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 12:37:19

US3522299

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:02:30
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 12:37:19

US3522299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:03:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 12:59:40

US3522299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:03:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 12:59:40

US3522299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

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 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:03:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 12:59:40

US3522299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 12:59:40

US3522299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:03:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 12:59:40

US3522299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:03:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '08:50'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 12:59:40

US3522299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered '21 Sep 2020 08:50'	System	21 Sep 2020 12:59:40

US3522299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:03:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	21 Sep 2020 12:59:40

US3522299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:03:17
User entered 'ONCE'	System	21 Sep 2020 12:59:40

US3522299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 12:59:40

US3522299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:03:27
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 12:55:43

US3522299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:03:27
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 12:55:43

US3522299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:03:27
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '08:45'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 12:55:43

US3522299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered '21 Sep 2020 08:45'	System	21 Sep 2020 12:55:43

US3522299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:59:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:03:33
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 12:56:06

US3522299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Sep 2020 12:56:06

US3522299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:03:33
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 12:56:06

US3522299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:03:33
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '08:49' reason for change: New Information	(b) (4), (b) (6)	21 Sep 2020 13:05:49
User entered '08:50'	(b) (4), (b) (6)	21 Sep 2020 12:56:06

US3522299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered '21 Sep 2020 08:49'	System	21 Sep 2020 13:05:49
User entered '21 Sep 2020 08:50'	System	21 Sep 2020 12:56:06

US3522299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Sep 2020 12:56:06

US3522299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:03:33
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 12:56:06

US3522299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:03:33
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 12:56:06

US3522299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered empty.	System	21 Sep 2020 12:56:06

US3522299

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:05:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 12:59:52

US3522299

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'I'	System	21 Sep 2020 12:59:52

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T09:22:38', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0ccab6ed-decf-43db-9dba-b6a517933d64'	System	21 Sep 2020 13:22:57
User entered 'Yes (Y)'	System	21 Sep 2020 13:22:57

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T09:22:44', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0ccab6ed-decf-43db-9dba-b6a517933d64'	System	21 Sep 2020 13:22:57
User entered '98.3'	System	21 Sep 2020 13:22:57

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T09:22:49', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0ccab6ed-decf-43db-9dba-b6a517933d64'	System	21 Sep 2020 13:22:57
User entered 'No (N)'	System	21 Sep 2020 13:22:57

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T09:22:52', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0ccab6ed-decf-43db-9dba-b6a517933d64'	System	21 Sep 2020 13:22:57
User entered '21 Sep 2020 09:22'	System	21 Sep 2020 13:22:57

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '21 Sep 2020 09:10'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '21 Sep 2020 11:40'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:03:36', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0172ae5e-053f-4d91-8164-cd5d72a39ece'	System	21 Sep 2020 22:04:17
User entered 'Yes (Y)'	System	21 Sep 2020 22:04:17

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:03:50', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0172ae5e-053f-4d91-8164-cd5d72a39ece'	System	21 Sep 2020 22:04:17
User entered '99.1'	System	21 Sep 2020 22:04:17

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:03:56', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0172ae5e-053f-4d91-8164-cd5d72a39ece'	System	21 Sep 2020 22:04:17
User entered 'Yes (Y)'	System	21 Sep 2020 22:04:17

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirmed on safety call day 36 and is line 5 in concom meds' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 10:53:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:04:03', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0172ae5e-053f-4d91-8164-cd5d72a39ece'	Sharon Mathys (b) (4)	29 Sep 2020 19:17:10
User entered '1'	System	21 Sep 2020 22:04:17
	System	21 Sep 2020 22:04:17
	System	21 Sep 2020 22:04:17

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:04:03', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0172ae5e-053f-4d91-8164-cd5d72a39ece'	System	21 Sep 2020 22:04:17
User entered '0'	System	21 Sep 2020 22:04:17

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:04:14', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0172ae5e-053f-4d91-8164-cd5d72a39ece'	System	21 Sep 2020 22:04:17
User entered '21 Sep 2020 18:04'	System	21 Sep 2020 22:04:17

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '21 Sep 2020 12:35'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 2'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:57:00', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0abc5023-4663-48ea-b3e7-31e769f031f1'	System	22 Sep 2020 21:57:27
User entered 'Yes (Y)'	System	22 Sep 2020 21:57:27

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:57:07', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0abc5023-4663-48ea-b3e7-31e769f031f1'	System	22 Sep 2020 21:57:27
User entered '98.7'	System	22 Sep 2020 21:57:27

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:57:12', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0abc5023-4663-48ea-b3e7-31e769f031f1'	System	22 Sep 2020 21:57:27
User entered 'Yes (Y)'	System	22 Sep 2020 21:57:27

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'yes ' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 13:52:08
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Kristin Eis (b) (4)	06 Oct 2020 13:58:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:57:19', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0abc5023-4663-48ea-b3e7-31e769f031f1'	(b) (4)	
User entered '1'	System	22 Sep 2020 21:57:27

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:57:19', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0abc5023-4663-48ea-b3e7-31e769f031f1' User entered '0'	System	22 Sep 2020 21:57:27
	System	22 Sep 2020 21:57:27

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:57:22', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0abc5023-4663-48ea-b3e7-31e769f031f1'	System	22 Sep 2020 21:57:27
User entered '22 Sep 2020 17:57'	System	22 Sep 2020 21:57:27

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 3'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-23T18:15:15', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '02e0eca7-ac18-4c69-8f9f-35b98d8ac4ac'	System	23 Sep 2020 22:15:35
User entered 'Yes (Y)'	System	23 Sep 2020 22:15:35

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-23T18:15:21', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '02e0eca7-ac18-4c69-8f9f-35b98d8ac4ac'	System	23 Sep 2020 22:15:35
User entered '99.9'	System	23 Sep 2020 22:15:35

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-23T18:15:26', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '02e0eca7-ac18-4c69-8f9f-35b98d8ac4ac'	System	23 Sep 2020 22:15:35
User entered 'No (N)'	System	23 Sep 2020 22:15:35

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-23T18:15:30', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '02e0eca7-ac18-4c69-8f9f-35b98d8ac4ac'	System	23 Sep 2020 22:15:35
User entered '23 Sep 2020 18:15'	System	23 Sep 2020 22:15:35

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 4'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-24T18:06:26', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd399fea7-25d2-4d10-9870-c94d4ba9e3be'	System	24 Sep 2020 22:06:46
User entered 'Yes (Y)'	System	24 Sep 2020 22:06:46

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-24T18:06:36', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd399fea7-25d2-4d10-9870-c94d4ba9e3be' User entered '98.3'	System	24 Sep 2020 22:06:46
	System	24 Sep 2020 22:06:46

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-24T18:06:40', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd399fea7-25d2-4d10-9870-c94d4ba9e3be'	System	24 Sep 2020 22:06:46
User entered 'No (N)'	System	24 Sep 2020 22:06:46

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-24T18:06:44', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd399fea7-25d2-4d10-9870-c94d4ba9e3be'	System	24 Sep 2020 22:06:46
User entered '24 Sep 2020 18:06'	System	24 Sep 2020 22:06:46

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 5'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-25T18:04:13', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd739fd8e-642b-4f89-8aec-c89fa28433e4'	System	25 Sep 2020 22:04:30
User entered 'Yes (Y)'	System	25 Sep 2020 22:04:30

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-25T18:04:21', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd739fd8e-642b-4f89-8aec-c89fa28433e4'	System	25 Sep 2020 22:04:30
User entered '98.3'	System	25 Sep 2020 22:04:30

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-25T18:04:25', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd739fd8e-642b-4f89-8aec-c89fa28433e4'	System	25 Sep 2020 22:04:30
User entered 'No (N)'	System	25 Sep 2020 22:04:30

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-25T18:04:28', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd739fd8e-642b-4f89-8aec-c89fa28433e4'	System	25 Sep 2020 22:04:30
User entered '25 Sep 2020 18:04'	System	25 Sep 2020 22:04:30

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 6'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-26T18:20:24', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8e3fa919-29f8-466c-b6bd-7020b5eabfad'	System	26 Sep 2020 22:20:43
User entered 'Yes (Y)'	System	26 Sep 2020 22:20:43

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-26T18:20:31', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8e3fa919-29f8-466c-b6bd-7020b5eabfad'	System	26 Sep 2020 22:20:43
User entered '98.4'	System	26 Sep 2020 22:20:43

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-26T18:20:35', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8e3fa919-29f8-466c-b6bd-7020b5eabfad'	System	26 Sep 2020 22:20:43
User entered 'No (N)'	System	26 Sep 2020 22:20:43

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-26T18:20:38', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8e3fa919-29f8-466c-b6bd-7020b5eabfad'	System	26 Sep 2020 22:20:43
User entered '26 Sep 2020 18:20'	System	26 Sep 2020 22:20:43

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 7'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-27T18:27:06', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a45fb8f1-5ae4-4a48-835f-751fa6bc6e7c'	System	27 Sep 2020 22:27:22
User entered 'Yes (Y)'	System	27 Sep 2020 22:27:22

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-27T18:27:12', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a45fb8f1-5ae4-4a48-835f-751fa6bc6e7c'	System	27 Sep 2020 22:27:22
User entered '98.7'	System	27 Sep 2020 22:27:22

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-27T18:27:15', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a45fb8f1-5ae4-4a48-835f-751fa6bc6e7c'	System	27 Sep 2020 22:27:22
User entered 'No (N)'	System	27 Sep 2020 22:27:22

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-27T18:27:19', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a45fb8f1-5ae4-4a48-835f-751fa6bc6e7c'	System	27 Sep 2020 22:27:22
User entered '27 Sep 2020 18:27'	System	27 Sep 2020 22:27:22

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T09:22:58', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'ac14f685-f08f-4714-9c02-e69e39dce9fa'	System	21 Sep 2020 13:23:21
User entered 'None (1)'	System	21 Sep 2020 13:23:21

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T09:23:08', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'ac14f685-f08f-4714-9c02-e69e39dce9fa'	System	21 Sep 2020 13:23:21
User entered 'No (N)'	System	21 Sep 2020 13:23:21

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T09:23:11', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'ac14f685-f08f-4714-9c02-e69e39dce9fa'	System	21 Sep 2020 13:23:21
User entered 'No (N)'	System	21 Sep 2020 13:23:21

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T09:23:15', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'ac14f685-f08f-4714-9c02-e69e39dce9fa'	System	21 Sep 2020 13:23:21
User entered 'None (1)'	System	21 Sep 2020 13:23:21

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T09:23:18', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'ac14f685-f08f-4714-9c02-e69e39dce9fa'	System	21 Sep 2020 13:23:21
User entered '21 Sep 2020 09:23'	System	21 Sep 2020 13:23:21

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '21 Sep 2020 09:10'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '21 Sep 2020 11:40'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:04:21', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'c7251af9-bcf5-4785-a98c-62e7a7011224'	System	21 Sep 2020 22:04:41
User entered 'None (1)'	System	21 Sep 2020 22:04:41

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:04:24', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'c7251af9-bcf5-4785-a98c-62e7a7011224'	System	21 Sep 2020 22:04:41
User entered 'No (N)'	System	21 Sep 2020 22:04:41

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:04:27', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'c7251af9-bcf5-4785-a98c-62e7a7011224'	System	21 Sep 2020 22:04:41
User entered 'No (N)'	System	21 Sep 2020 22:04:41

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:04:36', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'c7251af9-bcf5-4785-a98c-62e7a7011224'	System	21 Sep 2020 22:04:41
User entered 'None (1)'	System	21 Sep 2020 22:04:41

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:04:39', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'c7251af9-bcf5-4785-a98c-62e7a7011224'	System	21 Sep 2020 22:04:41
User entered '21 Sep 2020 18:04'	System	21 Sep 2020 22:04:41

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '21 Sep 2020 12:35'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 2'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:57:29', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '7f052a96-9ed2-4a45-ab72-0cf8074d0032'	System	22 Sep 2020 21:58:20
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 21:58:20

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:57:34', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '7f052a96-9ed2-4a45-ab72-0cf8074d0032'	System	22 Sep 2020 21:58:20
User entered 'Yes (Y)'	System	22 Sep 2020 21:58:20

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:57:57', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '7f052a96-9ed2-4a45-ab72-0cf8074d0032'	System	22 Sep 2020 21:58:20
User entered '4'	System	22 Sep 2020 21:58:20

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:58:07', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '7f052a96-9ed2-4a45-ab72-0cf8074d0032'	System	22 Sep 2020 21:58:20
User entered 'No (N)'	System	22 Sep 2020 21:58:20

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:58:11', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '7f052a96-9ed2-4a45-ab72-0cf8074d0032'	System	22 Sep 2020 21:58:20
User entered 'None (1)'	System	22 Sep 2020 21:58:20

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:58:14', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '7f052a96-9ed2-4a45-ab72-0cf8074d0032'	System	22 Sep 2020 21:58:20
User entered '22 Sep 2020 17:58'	System	22 Sep 2020 21:58:20

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 3'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-23T18:15:37', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '757ad877-5bc3-4a29-b5b1-df4d1c6363b8'	System	23 Sep 2020 22:16:26
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 22:16:26

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-23T18:15:41', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '757ad877-5bc3-4a29-b5b1-df4d1c6363b8'	System	23 Sep 2020 22:16:26
User entered 'Yes (Y)'	System	23 Sep 2020 22:16:26

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-23T18:16:05', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '757ad877-5bc3-4a29-b5b1-df4d1c6363b8' User entered '3'	System	23 Sep 2020 22:16:26
	System	23 Sep 2020 22:16:26

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-23T18:16:10', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '757ad877-5bc3-4a29-b5b1-df4d1c6363b8'	System	23 Sep 2020 22:16:26
User entered 'No (N)'	System	23 Sep 2020 22:16:26

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-23T18:16:19', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '757ad877-5bc3-4a29-b5b1-df4d1c6363b8'	System	23 Sep 2020 22:16:26
User entered 'None (1)'	System	23 Sep 2020 22:16:26

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-23T18:16:22', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '757ad877-5bc3-4a29-b5b1-df4d1c6363b8'	System	23 Sep 2020 22:16:26
User entered '23 Sep 2020 18:16'	System	23 Sep 2020 22:16:26

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 4'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-24T18:06:52', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd9feec71-8230-42e5-aff8-f5f75b03d46e'	System	24 Sep 2020 22:07:26
User entered 'None (1)'	System	24 Sep 2020 22:07:26

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-24T18:06:56', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd9feec71-8230-42e5-aff8-f5f75b03d46e'	System	24 Sep 2020 22:07:26
User entered 'Yes (Y)'	System	24 Sep 2020 22:07:26

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-24T18:07:03', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd9feec71-8230-42e5-aff8-f5f75b03d46e' User entered '3'	System	24 Sep 2020 22:07:26
	System	24 Sep 2020 22:07:26

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-24T18:07:11', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd9feec71-8230-42e5-aff8-f5f75b03d46e'	System	24 Sep 2020 22:07:26
User entered 'No (N)'	System	24 Sep 2020 22:07:26

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-24T18:07:18', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd9feec71-8230-42e5-aff8-f5f75b03d46e'	System	24 Sep 2020 22:07:26
User entered 'None (1)'	System	24 Sep 2020 22:07:26

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-24T18:07:21', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd9feec71-8230-42e5-aff8-f5f75b03d46e'	System	24 Sep 2020 22:07:26
User entered '24 Sep 2020 18:07'	System	24 Sep 2020 22:07:26

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 5'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-25T18:04:33', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '33cda3d9-a1af-4104-b4a9-719fedbcc40c'	System	25 Sep 2020 22:05:00
User entered 'None (1)'	System	25 Sep 2020 22:05:00

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-25T18:04:37', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '33cda3d9-a1af-4104-b4a9-719fedbcc40c'	System	25 Sep 2020 22:05:00
User entered 'No (N)'	System	25 Sep 2020 22:05:00

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-25T18:04:45', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '33cda3d9-a1af-4104-b4a9-719fedbcc40c'	System	25 Sep 2020 22:05:00
User entered 'No (N)'	System	25 Sep 2020 22:05:00

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-25T18:04:52', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '33cda3d9-a1af-4104-b4a9-719fedbcc40c'	System	25 Sep 2020 22:05:00
User entered 'None (1)'	System	25 Sep 2020 22:05:00

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-25T18:04:57', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '33cda3d9-a1af-4104-b4a9-719fedbcc40c'	System	25 Sep 2020 22:05:00
User entered '25 Sep 2020 18:04'	System	25 Sep 2020 22:05:00

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 6'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-26T18:20:43', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '4b455608-42e0-4aeb-90e0-36ffb5b36b33'	System	26 Sep 2020 22:21:07
User entered 'None (1)'	System	26 Sep 2020 22:21:07

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-26T18:20:47', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '4b455608-42e0-4aeb-90e0-36ffb5b36b33'	System	26 Sep 2020 22:21:07
User entered 'No (N)'	System	26 Sep 2020 22:21:07

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-26T18:20:53', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '4b455608-42e0-4aeb-90e0-36ffb5b36b33'	System	26 Sep 2020 22:21:07
User entered 'No (N)'	System	26 Sep 2020 22:21:07

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-26T18:21:01', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '4b455608-42e0-4aeb-90e0-36ffb5b36b33'	System	26 Sep 2020 22:21:07
User entered 'None (1)'	System	26 Sep 2020 22:21:07

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-26T18:21:05', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '4b455608-42e0-4aeb-90e0-36ffb5b36b33'	System	26 Sep 2020 22:21:07
User entered '26 Sep 2020 18:21'	System	26 Sep 2020 22:21:07

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 7'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-27T18:27:24', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '135d80ef-8fc0-4132-8e68-65725e462ddb'	System	27 Sep 2020 22:27:41
User entered 'None (1)'	System	27 Sep 2020 22:27:41

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-27T18:27:27', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '135d80ef-8fc0-4132-8e68-65725e462ddb'	System	27 Sep 2020 22:27:41
User entered 'No (N)'	System	27 Sep 2020 22:27:41

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-27T18:27:30', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '135d80ef-8fc0-4132-8e68-65725e462ddb'	System	27 Sep 2020 22:27:41
User entered 'No (N)'	System	27 Sep 2020 22:27:41

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-27T18:27:36', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '135d80ef-8fc0-4132-8e68-65725e462ddb'	System	27 Sep 2020 22:27:41
User entered 'None (1)'	System	27 Sep 2020 22:27:41

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-27T18:27:39', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '135d80ef-8fc0-4132-8e68-65725e462ddb'	System	27 Sep 2020 22:27:41
User entered '27 Sep 2020 18:27'	System	27 Sep 2020 22:27:41

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T09:23:23', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f4b6f486-fbaa-4d96-ab76-8751366c2c1b' User entered 'None (0)'	System	21 Sep 2020 13:23:45
	System	21 Sep 2020 13:23:45

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T09:23:26', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f4b6f486-fbaa-4d96-ab76-8751366c2c1b'	System	21 Sep 2020 13:23:45
User entered 'None (0)'	System	21 Sep 2020 13:23:45

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T09:23:29', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f4b6f486-fbaa-4d96-ab76-8751366c2c1b' User entered 'None (0)'	System	21 Sep 2020 13:23:45
	System	21 Sep 2020 13:23:45

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T09:23:32', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f4b6f486-fbaa-4d96-ab76-8751366c2c1b' User entered 'None (0)'	System	21 Sep 2020 13:23:45
	System	21 Sep 2020 13:23:45

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T09:23:34', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f4b6f486-fbaa-4d96-ab76-8751366c2c1b' User entered 'None (0)'	System	21 Sep 2020 13:23:45
	System	21 Sep 2020 13:23:45

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T09:23:37', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f4b6f486-fbaa-4d96-ab76-8751366c2c1b'	System	21 Sep 2020 13:23:45
User entered 'None (0)'	System	21 Sep 2020 13:23:45

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

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)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T09:23:40', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f4b6f486-fbaa-4d96-ab76-8751366c2c1b'	System	21 Sep 2020 13:23:45
User entered 'No (N)'	System	21 Sep 2020 13:23:45

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T09:23:43', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f4b6f486-fbaa-4d96-ab76-8751366c2c1b'	System	21 Sep 2020 13:23:45
User entered '21 Sep 2020 09:23'	System	21 Sep 2020 13:23:45

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '21 Sep 2020 09:10'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '21 Sep 2020 11:40'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:05:11', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a95d919c-e048-42fd-977f-4d10dfdb8d9e'	System	21 Sep 2020 22:05:39
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	21 Sep 2020 22:05:39

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:05:15', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a95d919c-e048-42fd-977f-4d10dfdb8d9e'	System	21 Sep 2020 22:05:39
User entered 'None (0)'	System	21 Sep 2020 22:05:39

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:05:18', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a95d919c-e048-42fd-977f-4d10dfdb8d9e'	System	21 Sep 2020 22:05:39
User entered 'None (0)'	System	21 Sep 2020 22:05:39

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:05:21', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a95d919c-e048-42fd-977f-4d10dfdb8d9e'	System	21 Sep 2020 22:05:39
User entered 'None (0)'	System	21 Sep 2020 22:05:39

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:05:24', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a95d919c-e048-42fd-977f-4d10dfdb8d9e'	System	21 Sep 2020 22:05:39
User entered 'None (0)'	System	21 Sep 2020 22:05:39

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:05:28', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a95d919c-e048-42fd-977f-4d10dfdb8d9e'	System	21 Sep 2020 22:05:39
User entered 'None (0)'	System	21 Sep 2020 22:05:39

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

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)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:05:33', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a95d919c-e048-42fd-977f-4d10dfdb8d9e'	System	21 Sep 2020 22:05:39
User entered 'No (N)'	System	21 Sep 2020 22:05:39

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-21T18:05:36', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a95d919c-e048-42fd-977f-4d10dfdb8d9e'	System	21 Sep 2020 22:05:39
User entered '21 Sep 2020 18:05'	System	21 Sep 2020 22:05:39

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '21 Sep 2020 12:35'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 2'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:58:31', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f1a5a3f3-546b-4534-b096-18cb816c5492'	System	22 Sep 2020 21:59:05
User entered 'No interference with activity (1)'	System	22 Sep 2020 21:59:05

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:58:36', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f1a5a3f3-546b-4534-b096-18cb816c5492'	System	22 Sep 2020 21:59:05
User entered 'None (0)'	System	22 Sep 2020 21:59:05

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:58:39', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f1a5a3f3-546b-4534-b096-18cb816c5492'	System	22 Sep 2020 21:59:05
User entered 'None (0)'	System	22 Sep 2020 21:59:05

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:58:41', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f1a5a3f3-546b-4534-b096-18cb816c5492'	System	22 Sep 2020 21:59:05
User entered 'None (0)'	System	22 Sep 2020 21:59:05

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:58:44', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f1a5a3f3-546b-4534-b096-18cb816c5492'	System	22 Sep 2020 21:59:05
User entered 'None (0)'	System	22 Sep 2020 21:59:05

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:58:47', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f1a5a3f3-546b-4534-b096-18cb816c5492'	System	22 Sep 2020 21:59:05
User entered 'None (0)'	System	22 Sep 2020 21:59:05

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

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)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:58:59', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f1a5a3f3-546b-4534-b096-18cb816c5492'	System	22 Sep 2020 21:59:05
User entered 'No (N)'	System	22 Sep 2020 21:59:05

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-22T17:59:02', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f1a5a3f3-546b-4534-b096-18cb816c5492'	System	22 Sep 2020 21:59:05
User entered '22 Sep 2020 17:59'	System	22 Sep 2020 21:59:05

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 3'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-23T18:16:28', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a6f4b9a4-6731-4ba1-89f9-ecd302613c4e' User entered 'None (0)'	System	23 Sep 2020 22:16:52
	System	23 Sep 2020 22:16:52

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-23T18:16:30', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a6f4b9a4-6731-4ba1-89f9-ecd302613c4e'	System	23 Sep 2020 22:16:52
User entered 'None (0)'	System	23 Sep 2020 22:16:52

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-23T18:16:33', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a6f4b9a4-6731-4ba1-89f9-ecd302613c4e' User entered 'None (0)'	System	23 Sep 2020 22:16:52
	System	23 Sep 2020 22:16:52

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-23T18:16:36', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a6f4b9a4-6731-4ba1-89f9-ecd302613c4e'	System	23 Sep 2020 22:16:52
User entered 'None (0)'	System	23 Sep 2020 22:16:52

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-23T18:16:38', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a6f4b9a4-6731-4ba1-89f9-ecd302613c4e'	System	23 Sep 2020 22:16:52
User entered 'None (0)'	System	23 Sep 2020 22:16:52

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-23T18:16:41', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a6f4b9a4-6731-4ba1-89f9-ecd302613c4e'	System	23 Sep 2020 22:16:52
User entered 'None (0)'	System	23 Sep 2020 22:16:52

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

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)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-23T18:16:46', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a6f4b9a4-6731-4ba1-89f9-ecd302613c4e'	System	23 Sep 2020 22:16:52
User entered 'No (N)'	System	23 Sep 2020 22:16:52

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-23T18:16:48', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a6f4b9a4-6731-4ba1-89f9-ecd302613c4e'	System	23 Sep 2020 22:16:52
User entered '23 Sep 2020 18:16'	System	23 Sep 2020 22:16:52

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 4'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-24T18:07:25', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '74543e2d-fdf0-4fc5-9ec6-0c0a469d744c'	System	24 Sep 2020 22:07:49
User entered 'None (0)'	System	24 Sep 2020 22:07:49

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-24T18:07:28', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '74543e2d-fdf0-4fc5-9ec6-0c0a469d744c'	System	24 Sep 2020 22:07:49
User entered 'None (0)'	System	24 Sep 2020 22:07:49

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-24T18:07:30', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '74543e2d-fdf0-4fc5-9ec6-0c0a469d744c'	System	24 Sep 2020 22:07:49
User entered 'None (0)'	System	24 Sep 2020 22:07:49

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-24T18:07:32', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '74543e2d-fdf0-4fc5-9ec6-0c0a469d744c'	System	24 Sep 2020 22:07:49
User entered 'None (0)'	System	24 Sep 2020 22:07:49

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-24T18:07:36', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '74543e2d-fdf0-4fc5-9ec6-0c0a469d744c'	System	24 Sep 2020 22:07:49
User entered 'None (0)'	System	24 Sep 2020 22:07:49

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-24T18:07:39', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '74543e2d-fdf0-4fc5-9ec6-0c0a469d744c'	System	24 Sep 2020 22:07:49
User entered 'None (0)'	System	24 Sep 2020 22:07:49

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

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)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-24T18:07:42', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '74543e2d-fdf0-4fc5-9ec6-0c0a469d744c'	System	24 Sep 2020 22:07:49
User entered 'No (N)'	System	24 Sep 2020 22:07:49

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-24T18:07:45', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '74543e2d-fdf0-4fc5-9ec6-0c0a469d744c'	System	24 Sep 2020 22:07:49
User entered '24 Sep 2020 18:07'	System	24 Sep 2020 22:07:49

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 5'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-25T18:05:01', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a0765e8a-c45b-477a-b751-d56dcfc1658b'	System	25 Sep 2020 22:05:27
User entered 'None (0)'	System	25 Sep 2020 22:05:27

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-25T18:05:04', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a0765e8a-c45b-477a-b751-d56dcfc1658b' User entered 'None (0)'	System	25 Sep 2020 22:05:27
	System	25 Sep 2020 22:05:27

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-25T18:05:06', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a0765e8a-c45b-477a-b751-d56dcfc1658b'	System	25 Sep 2020 22:05:27
User entered 'None (0)'	System	25 Sep 2020 22:05:27

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-25T18:05:08', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a0765e8a-c45b-477a-b751-d56dcfc1658b' User entered 'None (0)'	System	25 Sep 2020 22:05:27
	System	25 Sep 2020 22:05:27

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-25T18:05:10', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a0765e8a-c45b-477a-b751-d56dcfc1658b'	System	25 Sep 2020 22:05:27
User entered 'None (0)'	System	25 Sep 2020 22:05:27

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-25T18:05:12', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a0765e8a-c45b-477a-b751-d56dcfc1658b'	System	25 Sep 2020 22:05:27
User entered 'None (0)'	System	25 Sep 2020 22:05:27

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

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)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-25T18:05:20', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a0765e8a-c45b-477a-b751-d56dcfc1658b'	System	25 Sep 2020 22:05:27
User entered 'No (N)'	System	25 Sep 2020 22:05:27

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-25T18:05:22', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a0765e8a-c45b-477a-b751-d56dcfc1658b'	System	25 Sep 2020 22:05:27
User entered '25 Sep 2020 18:05'	System	25 Sep 2020 22:05:27

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 6'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-26T18:21:09', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'e70a6f7d-4cfb-4f37-9393-2f53ffefa659'	System	26 Sep 2020 22:21:32
User entered 'None (0)'	System	26 Sep 2020 22:21:32

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-26T18:21:12', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'e70a6f7d-4cfb-4f37-9393-2f53ffefa659'	System	26 Sep 2020 22:21:32
User entered 'None (0)'	System	26 Sep 2020 22:21:32

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-26T18:21:14', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'e70a6f7d-4cfb-4f37-9393-2f53ffefa659'	System	26 Sep 2020 22:21:32
User entered 'None (0)'	System	26 Sep 2020 22:21:32

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-26T18:21:16', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'e70a6f7d-4cfb-4f37-9393-2f53ffefa659'	System	26 Sep 2020 22:21:32
User entered 'None (0)'	System	26 Sep 2020 22:21:32

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-26T18:21:18', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'e70a6f7d-4cfb-4f37-9393-2f53ffefa659'	System	26 Sep 2020 22:21:32
User entered 'None (0)'	System	26 Sep 2020 22:21:32

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-26T18:21:22', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'e70a6f7d-4cfb-4f37-9393-2f53ffefa659'	System	26 Sep 2020 22:21:32
User entered 'None (0)'	System	26 Sep 2020 22:21:32

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

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)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-26T18:21:27', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'e70a6f7d-4cfb-4f37-9393-2f53ffefa659'	System	26 Sep 2020 22:21:32
User entered 'No (N)'	System	26 Sep 2020 22:21:32

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-26T18:21:29', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'e70a6f7d-4cfb-4f37-9393-2f53ffefa659'	System	26 Sep 2020 22:21:32
User entered '26 Sep 2020 18:21'	System	26 Sep 2020 22:21:32

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	21 Sep 2020 12:59:40
User entered 'Day 7'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-27T18:27:43', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'ea86084a-d481-48c0-adfc-be3cf5ea6dc8'	System	27 Sep 2020 22:28:09
User entered 'None (0)'	System	27 Sep 2020 22:28:09

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-27T18:27:51', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'ea86084a-d481-48c0-adfc-be3cf5ea6dc8'	System	27 Sep 2020 22:28:09
User entered 'None (0)'	System	27 Sep 2020 22:28:09

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-27T18:27:54', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'ea86084a-d481-48c0-adfc-be3cf5ea6dc8'	System	27 Sep 2020 22:28:09
User entered 'None (0)'	System	27 Sep 2020 22:28:09

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-27T18:27:56', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'ea86084a-d481-48c0-adfc-be3cf5ea6dc8'	System	27 Sep 2020 22:28:09
User entered 'None (0)'	System	27 Sep 2020 22:28:09

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-27T18:27:58', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'ea86084a-d481-48c0-adfc-be3cf5ea6dc8'	System	27 Sep 2020 22:28:09
User entered 'None (0)'	System	27 Sep 2020 22:28:09

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-27T18:28:00', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'ea86084a-d481-48c0-adfc-be3cf5ea6dc8'	System	27 Sep 2020 22:28:09
User entered 'None (0)'	System	27 Sep 2020 22:28:09

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

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)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-27T18:28:03', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'ea86084a-d481-48c0-adfc-be3cf5ea6dc8'	System	27 Sep 2020 22:28:09
User entered 'No (N)'	System	27 Sep 2020 22:28:09

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-09-27T18:28:05', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'ea86084a-d481-48c0-adfc-be3cf5ea6dc8'	System	27 Sep 2020 22:28:09
User entered '27 Sep 2020 18:28'	System	27 Sep 2020 22:28:09

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 12:59:40

US3522299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 12:59:40

US3522299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 19:13:53

US3522299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 19:13:53

US3522299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Sep 2020 19:13:53

US3522299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'AFTERNOON OF INJECTION TOOK 650 MG OF TYLENOL. HEADACHE SUBSIDED. ediary matched,' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4) (b) (4)	29 Sep 2020 19:10:39
User entered 'Had headache the afternoon of injection for which she took 650 mg of Tylenol. Headache subsided after that point. patient also noted slight temperature increase on day of injection and 2 days after injection; both readings were under 100 degrees F.' (non-conformant).	(b) (4), (b) (6)	28 Sep 2020 19:13:53

US3522299

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:04
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:14:06

US3522299

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'I'	System	28 Sep 2020 19:14:06

US3522299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:25:15
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:16:07

US3522299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:25:15
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4)	06 Oct 2020 13:54:30
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 15:16:07

US3522299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:25:15
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Kristin Eis (b) (4)	06 Oct 2020 13:57:39
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	
	(b) (4), (b) (6)	05 Oct 2020 15:16:07

US3522299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:25:15
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'see source' reason for change: Data Entry Error	Kristin Eis (b) (4)	06 Oct 2020 14:08:48
User entered empty; reason for change Data Entry Error	Kristin Eis (b) (4)	06 Oct 2020 13:57:39
User entered 'Voicemail left'	(b) (4), (b) (6)	05 Oct 2020 15:16:07

US3522299

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:25:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	Kristin Eis (b) (4)	06 Oct 2020 14:08:51

US3522299

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'I'	System	06 Oct 2020 14:08:51

US3522299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:32:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Yes (Y)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	04 Mar 2021 19:27:01

US3522299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:32:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered '12 Oct 2020'	(b) (4) Sharon Mathys (b) (4) (b) (4)	04 Mar 2021 19:27:01

US3522299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:32:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	04 Mar 2021 19:27:01

US3522299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:32:16
User closed query 'Per DM CLR: Review specified comment = PATIENT IS STILL HAVING MILD HEADACHES, MAY BE RELATED TO SINUS PRESSURE. Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:35:19
Query 'Per DM CLR: Review specified comment = PATIENT IS STILL HAVING MILD HEADACHES, MAY BE RELATED TO SINUS PRESSURE. Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' answered with 'Study physician cleared' (Site from DM).	Alayna Wilder (b) (4) (b) (4)	16 Mar 2021 23:55:52
User opened query 'Per DM CLR: Review specified comment = PATIENT IS STILL HAVING MILD HEADACHES, MAY BE RELATED TO SINUS PRESSURE. Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 13:36:07
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:41
User entered 'PATIENT IS STILL HAVING MILD HEADACHES, MAY BE RELATED TO SINUS PRESSURE CONTINUING TO TAKE TYLENOL, 1-2 TIMES PER DAY AS NEEDED, for HEADACHE..FLU SHOT 09-OCT-2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	04 Mar 2021 19:28:07

US3522299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Patient is still having mild headaches, thinks that it may be related to sinus pressure but isn't sure, is continuing to take Tylenol, 1-2 times per day as needed, which is effective in getting rid of the headache. The headaches are not interfering with her daily life. Patient also had flu shot 09-OCT-2020.' (non-conformant).	Sharon Mathys (b) (4)	04 Mar 2021 19:27:01

US3522299

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User closed query 'Please enter Safety Call details' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:32:23
Query 'Please enter Safety Call details' answered with Sharon Mathys 'added' (Site from CRA).	(b) (4)	04 Mar 2021 19:28:13
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:26:04
User opened query 'Please enter Safety Call details' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:26:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 11:28:40

US3522299

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'I'	System	23 Oct 2020 11:28:40

US3522299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:26:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 11:29:21

US3522299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:26:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 11:29:21

US3522299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

[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 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:26:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 11:29:21

US3522299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'VISIT3'	System	23 Oct 2020 11:29:21

US3522299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:27:08
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 11:39:18

US3522299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:27:08
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 11:39:18

US3522299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:27:08
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '07:36'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 11:39:18

US3522299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered '23 Oct 2020 07:36'	System	23 Oct 2020 11:39:18

US3522299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:27:08
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '98' F	(b) (4), (b) (6)	23 Oct 2020 11:39:18

US3522299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:27:08
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 11:39:18

US3522299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:27:08
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 11:39:18

US3522299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:27:08
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '70'	(b) (4), (b) (6)	23 Oct 2020 11:39:18

US3522299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'bpm'	System	23 Oct 2020 11:39:18

US3522299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:27:08
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '16'	(b) (4), (b) (6)	23 Oct 2020 11:39:18

US3522299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'breaths/min'	System	23 Oct 2020 11:39:18

US3522299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:27:08
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '147'	(b) (4), (b) (6)	23 Oct 2020 11:39:18

US3522299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'mmHg'	System	23 Oct 2020 11:39:18

US3522299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:27:08
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '92'	(b) (4), (b) (6)	23 Oct 2020 11:39:18

US3522299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'mmHg'	System	23 Oct 2020 11:39:18

US3522299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45

US3522299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45

US3522299

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:28:27
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 11:39:24

US3522299

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:28:27
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 11:39:24

US3522299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:28:33
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 11:49:10

US3522299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:28:33
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 11:49:10

US3522299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:28:33
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered '07:50'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 11:49:10

US3522299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered '23 Oct 2020 07:50'	System	23 Oct 2020 11:49:10

US3522299

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:28:36
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 11:49:15

US3522299

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:44:45
User entered 'I'	System	23 Oct 2020 11:49:15

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 64'	System	24 Aug 2020 13:28:27

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-10-25T11:35:35', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8d93112b-4e88-479e-8d53-1e28d1740fe6'	System	25 Oct 2020 15:35:54
User entered 'No (N)'	System	25 Oct 2020 15:35:54

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Have you been exposed to someone with 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 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-10-25T11:35:41', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8d93112b-4e88-479e-8d53-1e28d1740fe6'	System	25 Oct 2020 15:35:54
User entered 'No (N)'	System	25 Oct 2020 15:35:54

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-10-25T11:35:49', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '8d93112b-4e88-479e-8d53-1e28d1740fe6'	System	25 Oct 2020 15:35:54
User entered '25 Oct 2020 11:35:49'	System	25 Oct 2020 15:35:54

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 13:28:27

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 71'	System	24 Aug 2020 13:28:27

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-11-03T12:40:55', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a37aac45-9951-4d6f-8d3c-05c9c68ae11b'	System	03 Nov 2020 17:41:17
User entered 'No (N)'	System	03 Nov 2020 17:41:17

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Have you been exposed to someone with 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 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-11-03T12:41:01', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a37aac45-9951-4d6f-8d3c-05c9c68ae11b'	System	03 Nov 2020 17:41:17
User entered 'No (N)'	System	03 Nov 2020 17:41:17

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-11-03T12:41:08', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a37aac45-9951-4d6f-8d3c-05c9c68ae11b'	System	03 Nov 2020 17:41:17
User entered '03 Nov 2020 12:41:08'	System	03 Nov 2020 17:41:17

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 13:28:27

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered 'Day 78'	System	24 Aug 2020 13:28:27

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-11-09T13:33:20', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'ef7c8e21-eec1-42a4-a0ef-17e8cf41ecf3'	System	09 Nov 2020 18:33:36
User entered 'No (N)'	System	09 Nov 2020 18:33:36

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Have you been exposed to someone with 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 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-11-09T13:33:25', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'ef7c8e21-eec1-42a4-a0ef-17e8cf41ecf3'	System	09 Nov 2020 18:33:36
User entered 'No (N)'	System	09 Nov 2020 18:33:36

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-11-09T13:33:31', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'ef7c8e21-eec1-42a4-a0ef-17e8cf41ecf3'	System	09 Nov 2020 18:33:36
User entered '09 Nov 2020 13:33:31'	System	09 Nov 2020 18:33:36

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 13:28:27

US3522299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:11
Data entry locked.	System	24 Aug 2020 13:28:27
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 13:28:27

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	Bollam Gouthami (3547 - 19 Mar 2021 06:38:29 Bollam@gs1)	
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'Pt saw PCP 20 NOV 2020 and discovered BP of 160/112. Pt states her BP has been elevated in the past but was not high enough to worry about. Was started on Amlodipine 5 mg daily. Pt states PCP wants her to continue taking this while awaiting some lab work and could possibly change medication following. Pt verbalized understanding and will reach out to study staff with any changes AE and medication was already previously added. ' (Site from DM).	michael garcia (2330 - 17 Mar 2021 13:41:15 mgarcia10261)	
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	Mariel Grace Lacuesta (2272 - marielgrace1)	06 Mar 2021 13:06:05

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2020-11-25T07:06:55', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'bf89f3b1-c808-4180-beed-ba39a3a2a91f'	System	25 Nov 2020 12:07:46
User entered 'Yes (Y)'	System	25 Nov 2020 12:07:46

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2020-11-25T07:07:01', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'bf89f3b1-c808-4180-beed-ba39a3a2a91f'	System	25 Nov 2020 12:07:46
User entered 'No (N)'	System	25 Nov 2020 12:07:46

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-11-25T07:07:06', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'bf89f3b1-c808-4180-beed-ba39a3a2a91f'	System	25 Nov 2020 12:07:46
User entered 'No (N)'	System	25 Nov 2020 12:07:46

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-11-25T07:07:13', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'bf89f3b1-c808-4180-beed-ba39a3a2a91f'	System	25 Nov 2020 12:07:46
User entered 'Yes (Y)'	System	25 Nov 2020 12:07:46

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-11-25T07:07:23', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'bf89f3b1-c808-4180-beed-ba39a3a2a91f'	System	25 Nov 2020 12:07:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Nov 2020 12:07:46

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-11-25T07:07:36', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'bf89f3b1-c808-4180-beed-ba39a3a2a91f'	System	25 Nov 2020 12:07:46
User entered '25 Nov 2020 07:07:36'	System	25 Nov 2020 12:07:46

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2020-12-06T18:57:02', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '86c6758f-f56e-4a12-a4c3-31f9ce7c9628'	System	06 Dec 2020 23:57:16
User entered 'No (N)'	System	06 Dec 2020 23:57:16

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2020-12-06T18:57:08', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '86c6758f-f56e-4a12-a4c3-31f9ce7c9628'	System	06 Dec 2020 23:57:16
User entered 'No (N)'	System	06 Dec 2020 23:57:16

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-12-06T18:57:12', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '86c6758f-f56e-4a12-a4c3-31f9ce7c9628'	System	06 Dec 2020 23:57:16
User entered '06 Dec 2020 18:57:12'	System	06 Dec 2020 23:57:16

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2020-12-09T09:58:18', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'e67cb937-9b9a-47a1-9e94-dbab7609fa30'	System	09 Dec 2020 14:58:36
User entered 'No (N)'	System	09 Dec 2020 14:58:36

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2020-12-09T09:58:26', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'e67cb937-9b9a-47a1-9e94-dbab7609fa30'	System	09 Dec 2020 14:58:36
User entered 'No (N)'	System	09 Dec 2020 14:58:36

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-12-09T09:58:31', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'e67cb937-9b9a-47a1-9e94-dbab7609fa30'	System	09 Dec 2020 14:58:36
User entered '09 Dec 2020 09:58:31'	System	09 Dec 2020 14:58:36

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2020-12-16T04:56:01', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '149fe553-0498-42c7-a04a-dccc2d847717'	System	16 Dec 2020 09:56:49
User entered 'Yes (Y)'	System	16 Dec 2020 09:56:49

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2020-12-16T04:56:05', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '149fe553-0498-42c7-a04a-dccc2d847717'	System	16 Dec 2020 09:56:49
User entered 'No (N)'	System	16 Dec 2020 09:56:49

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-12-16T04:56:11', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '149fe553-0498-42c7-a04a-dccc2d847717'	System	16 Dec 2020 09:56:49
User entered 'No (N)'	System	16 Dec 2020 09:56:49

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-12-16T04:56:18', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '149fe553-0498-42c7-a04a-dccc2d847717'	System	16 Dec 2020 09:56:49
User entered 'Yes (Y)'	System	16 Dec 2020 09:56:49

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-12-16T04:56:30', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '149fe553-0498-42c7-a04a-dccc2d847717'	System	16 Dec 2020 09:56:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Dec 2020 09:56:49

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-12-16T04:56:39', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '149fe553-0498-42c7-a04a-dccc2d847717'	System	16 Dec 2020 09:56:49
User entered '16 Dec 2020 04:56:39'	System	16 Dec 2020 09:56:49

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2020-12-23T06:38:57', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '60887f38-133f-441f-bb12-ff4f4c65aa02'	System	23 Dec 2020 11:39:13
User entered 'No (N)'	System	23 Dec 2020 11:39:13

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2020-12-23T06:39:06', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '60887f38-133f-441f-bb12-ff4f4c65aa02'	System	23 Dec 2020 11:39:13
User entered 'No (N)'	System	23 Dec 2020 11:39:13

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2020-12-23T06:39:09', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '60887f38-133f-441f-bb12-ff4f4c65aa02'	System	23 Dec 2020 11:39:13
User entered '23 Dec 2020 06:39:09'	System	23 Dec 2020 11:39:13

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2021-01-06T13:07:20', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'c5945915-3257-46a3-bc46-eb12642da812'	System	06 Jan 2021 18:07:52
User entered 'No (N)'	System	06 Jan 2021 18:07:52

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2021-01-06T13:07:25', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'c5945915-3257-46a3-bc46-eb12642da812'	System	06 Jan 2021 18:07:52
User entered 'No (N)'	System	06 Jan 2021 18:07:52

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-01-06T13:07:46', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'c5945915-3257-46a3-bc46-eb12642da812'	System	06 Jan 2021 18:07:52
User entered '06 Jan 2021 13:07:46'	System	06 Jan 2021 18:07:52

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2021-01-15T13:47:15', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'cedb227b-90fd-46f1-aa61-ebf74226f779'	System	15 Jan 2021 18:47:26
User entered 'No (N)'	System	15 Jan 2021 18:47:26

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2021-01-15T13:47:19', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'cedb227b-90fd-46f1-aa61-ebf74226f779'	System	15 Jan 2021 18:47:26
User entered 'No (N)'	System	15 Jan 2021 18:47:26

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-01-15T13:47:22', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'cedb227b-90fd-46f1-aa61-ebf74226f779' User entered '15 Jan 2021 13:47:22'	System	15 Jan 2021 18:47:26
	System	15 Jan 2021 18:47:26

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2021-01-23T18:49:40', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd0d4d12a-0055-4efe-af89-def1cbbcfef7'	System	23 Jan 2021 23:49:56
User entered 'No (N)'	System	23 Jan 2021 23:49:56

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2021-01-23T18:49:48', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd0d4d12a-0055-4efe-af89-def1cbbcfef7'	System	23 Jan 2021 23:49:56
User entered 'No (N)'	System	23 Jan 2021 23:49:56

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-01-23T18:49:52', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd0d4d12a-0055-4efe-af89-def1cbbcfef7'	System	23 Jan 2021 23:49:56
User entered '23 Jan 2021 18:49:52'	System	23 Jan 2021 23:49:56

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2021-02-07T19:27:04', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '01916e46-d849-4fb0-9fd2-3fe038fb6887'	System	08 Feb 2021 00:27:17
User entered 'No (N)'	System	08 Feb 2021 00:27:17

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2021-02-07T19:27:10', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '01916e46-d849-4fb0-9fd2-3fe038fb6887'	System	08 Feb 2021 00:27:17
User entered 'No (N)'	System	08 Feb 2021 00:27:17

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-02-07T19:27:14', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '01916e46-d849-4fb0-9fd2-3fe038fb6887'	System	08 Feb 2021 00:27:17
User entered '07 Feb 2021 19:27:14'	System	08 Feb 2021 00:27:17

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2021-02-10T14:06:06', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '50e7de3a-59c2-4a9f-ba5a-45326af5e880'	System	10 Feb 2021 19:06:20
User entered 'No (N)'	System	10 Feb 2021 19:06:20

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2021-02-10T14:06:11', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '50e7de3a-59c2-4a9f-ba5a-45326af5e880'	System	10 Feb 2021 19:06:20
User entered 'No (N)'	System	10 Feb 2021 19:06:20

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-02-10T14:06:15', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '50e7de3a-59c2-4a9f-ba5a-45326af5e880'	System	10 Feb 2021 19:06:20
User entered '10 Feb 2021 14:06:15'	System	10 Feb 2021 19:06:20

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2021-02-17T17:27:32', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0ef4769b-7636-4631-9f7c-e9dab8d1da8f'	System	17 Feb 2021 22:27:47
User entered 'No (N)'	System	17 Feb 2021 22:27:47

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2021-02-17T17:27:37', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0ef4769b-7636-4631-9f7c-e9dab8d1da8f'	System	17 Feb 2021 22:27:47
User entered 'No (N)'	System	17 Feb 2021 22:27:47

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-02-17T17:27:41', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '0ef4769b-7636-4631-9f7c-e9dab8d1da8f' User entered '17 Feb 2021 17:27:41'	System	17 Feb 2021 22:27:47
	System	17 Feb 2021 22:27:47

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2021-02-27T20:09:10', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f194b63b-c310-4e69-b34c-e3b4ea6a283a'	System	28 Feb 2021 01:10:42
User entered 'No (N)'	System	28 Feb 2021 01:10:42

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2021-02-27T20:09:14', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f194b63b-c310-4e69-b34c-e3b4ea6a283a'	System	28 Feb 2021 01:10:42
User entered 'No (N)'	System	28 Feb 2021 01:10:42

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-02-27T20:09:17', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'f194b63b-c310-4e69-b34c-e3b4ea6a283a'	System	28 Feb 2021 01:10:42
User entered '27 Feb 2021 20:09:17'	System	28 Feb 2021 01:10:42

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2021-03-04T05:44:06', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '015ef905-2b3c-47cb-a0a9-1a6faf838070'	System	04 Mar 2021 10:44:21
User entered 'No (N)'	System	04 Mar 2021 10:44:21

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2021-03-04T05:44:10', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '015ef905-2b3c-47cb-a0a9-1a6faf838070'	System	04 Mar 2021 10:44:21
User entered 'No (N)'	System	04 Mar 2021 10:44:21

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-03-04T05:44:15', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '015ef905-2b3c-47cb-a0a9-1a6faf838070'	System	04 Mar 2021 10:44:21
User entered '04 Mar 2021 05:44:15'	System	04 Mar 2021 10:44:21

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2021-03-10T13:14:39', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '1a434345-7849-4835-8c12-1703d3a170f4'	System	10 Mar 2021 18:16:58
User entered 'No (N)'	System	10 Mar 2021 18:16:58

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2021-03-10T13:14:43', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '1a434345-7849-4835-8c12-1703d3a170f4'	System	10 Mar 2021 18:16:58
User entered 'No (N)'	System	10 Mar 2021 18:16:58

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-03-10T13:14:47', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '1a434345-7849-4835-8c12-1703d3a170f4'	System	10 Mar 2021 18:16:58
User entered '10 Mar 2021 13:14:47'	System	10 Mar 2021 18:16:58

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2021-03-17T10:41:34', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '984ac754-1256-4e98-9f9a-664f3c8f0437'	System	17 Mar 2021 14:41:46
User entered 'No (N)'	System	17 Mar 2021 14:41:46

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2021-03-17T10:41:38', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '984ac754-1256-4e98-9f9a-664f3c8f0437'	System	17 Mar 2021 14:41:46
User entered 'No (N)'	System	17 Mar 2021 14:41:46

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-03-17T10:41:42', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '984ac754-1256-4e98-9f9a-664f3c8f0437'	System	17 Mar 2021 14:41:46
User entered '17 Mar 2021 10:41:42'	System	17 Mar 2021 14:41:46

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2021-03-31T19:50:26', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '05eeac8b-8c46-4458-a625-844462a4bfe7'	System	31 Mar 2021 23:51:10
User entered 'Yes (Y)'	System	31 Mar 2021 23:51:10

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2021-03-31T19:50:31', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '05eeac8b-8c46-4458-a625-844462a4bfe7'	System	31 Mar 2021 23:51:10
User entered 'No (N)'	System	31 Mar 2021 23:51:10

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-03-31T19:50:37', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '05eeac8b-8c46-4458-a625-844462a4bfe7'	System	31 Mar 2021 23:51:10
User entered 'No (N)'	System	31 Mar 2021 23:51:10

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-03-31T19:50:44', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '05eeac8b-8c46-4458-a625-844462a4bfe7'	System	31 Mar 2021 23:51:10
User entered 'Yes (Y)'	System	31 Mar 2021 23:51:10

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-03-31T19:50:53', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '05eeac8b-8c46-4458-a625-844462a4bfe7'	System	31 Mar 2021 23:51:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Mar 2021 23:51:10

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-03-31T19:50:58', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '05eeac8b-8c46-4458-a625-844462a4bfe7'	System	31 Mar 2021 23:51:10
User entered '31 Mar 2021 19:50:58'	System	31 Mar 2021 23:51:10

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2021-04-08T08:46:14', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '58433fa2-428b-43fc-bd6f-bab11bc08234'	System	08 Apr 2021 12:46:31
User entered 'No (N)'	System	08 Apr 2021 12:46:31

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2021-04-08T08:46:22', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '58433fa2-428b-43fc-bd6f-bab11bc08234'	System	08 Apr 2021 12:46:31
User entered 'No (N)'	System	08 Apr 2021 12:46:31

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-04-08T08:46:25', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '58433fa2-428b-43fc-bd6f-bab11bc08234'	System	08 Apr 2021 12:46:31
User entered '08 Apr 2021 08:46:25'	System	08 Apr 2021 12:46:31

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2021-04-15T12:35:49', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a5e926fb-d506-4181-8f8c-ad614b9864cb'	System	15 Apr 2021 16:36:03
User entered 'No (N)'	System	15 Apr 2021 16:36:03

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2021-04-15T12:35:53', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a5e926fb-d506-4181-8f8c-ad614b9864cb'	System	15 Apr 2021 16:36:03
User entered 'No (N)'	System	15 Apr 2021 16:36:03

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-04-15T12:35:59', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'a5e926fb-d506-4181-8f8c-ad614b9864cb'	System	15 Apr 2021 16:36:03
User entered '15 Apr 2021 12:35:59'	System	15 Apr 2021 16:36:03

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2021-04-21T11:58:46', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'b15291ae-f884-49a9-b18b-f23cffe3423f'	System	21 Apr 2021 15:58:55
User entered 'No (N)'	System	21 Apr 2021 15:58:55

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2021-04-21T11:58:48', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'b15291ae-f884-49a9-b18b-f23cffe3423f'	System	21 Apr 2021 15:58:55
User entered 'No (N)'	System	21 Apr 2021 15:58:55

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-04-21T11:58:52', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'b15291ae-f884-49a9-b18b-f23cffe3423f' User entered '21 Apr 2021 11:58:52'	System	21 Apr 2021 15:58:55
	System	21 Apr 2021 15:58:55

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[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 (3c45bcde51c484d5)', Time: '2021-04-28T16:41:40', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd148ddcd-7f0a-4c91-9498-42fa73287dc5'	System	28 Apr 2021 23:10:21
User entered 'No (N)'	System	28 Apr 2021 23:10:21

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

Have you been exposed to someone with 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 (3c45bcde51c484d5)', Time: '2021-04-28T16:41:44', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd148ddcd-7f0a-4c91-9498-42fa73287dc5'	System	28 Apr 2021 23:10:21
User entered 'No (N)'	System	28 Apr 2021 23:10:21

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-04-28T16:41:51', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: 'd148ddcd-7f0a-4c91-9498-42fa73287dc5'	System	28 Apr 2021 23:10:21
User entered '28 Apr 2021 16:41:51'	System	28 Apr 2021 23:10:21

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:31:40

US3522299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:40
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:31:40

US3522299

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:59:48

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)	24 Apr 2021 20:18:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-02-27T20:09:25', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '2a5e848c-6d18-47e0-a473-baa5448e1cae'	System	28 Feb 2021 01:10:57
User entered 'No (N)'	System	28 Feb 2021 01:10:57

US3522299

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:59:48

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:18:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c45bcde51c484d5)', Time: '2021-02-27T20:09:33', User OID: 'PatientReportedOutcome (US3522299)', ODM File OID: '2a5e848c-6d18-47e0-a473-baa5448e1cae'	System	28 Feb 2021 01:10:57
User entered '27 Feb 2021 20:09:33'	System	28 Feb 2021 01:10:57

US3522299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:09:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	16 Nov 2020 19:43:47
	(b) (4)	

US3522299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:09:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered '16 Nov 2020'	(b) (4) Alandra White (b) (4) (b) (4)	16 Nov 2020 19:43:47

US3522299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:09:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alandra White (b) (4) (b) (4)	16 Nov 2020 19:43:47

US3522299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:09:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	(b) (4) Alandra White (b) (4) (b) (4)	16 Nov 2020 19:43:47

US3522299

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:09:04
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	16 Nov 2020 19:43:53
	(b) (4)	

US3522299

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:44
User entered 'I'	System	16 Nov 2020 19:43:53

US3522299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:36:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:13:38
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Dec 2020 19:25:05

US3522299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:36:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:13:38
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered '18 Dec 2020'	(b) (4), (b) (6)	18 Dec 2020 19:25:05

US3522299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:36:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:13:38
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Dec 2020 19:25:05

US3522299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:36:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:13:38
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	(b) (4), (b) (6)	18 Dec 2020 19:25:05

US3522299

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:36:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:15:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Dec 2020 19:25:09

US3522299

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:36:58
User entered 'I'	System	18 Dec 2020 19:25:09

US3522299

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:36:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	19 Jan 2021 17:29:20

US3522299

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:36:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered '19 Jan 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	19 Jan 2021 17:29:20

US3522299

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:36:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	19 Jan 2021 17:29:20

US3522299

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:36:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Blood pressure has been improving, today was 140s/80 and will be following up with PCP on 22 Jan 2021. Otherwise, no other ongoing or new AE reported; no other health changes or covid-19 exposures'	(b) (4) Yaman Ahmed (b) (4)	19 Jan 2021 17:29:20

US3522299

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:36:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	19 Jan 2021 17:29:28

US3522299

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:36:58
User entered 'I'	System	19 Jan 2021 17:29:28

US3522299

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:36:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	16 Feb 2021 19:49:05

US3522299

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:36:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered '16 Feb 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	16 Feb 2021 19:49:05

US3522299

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:36:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	16 Feb 2021 19:49:05

US3522299

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:36:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk'	(b) (4) Yaman Ahmed (b) (4)	16 Feb 2021 19:49:05

US3522299

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:36:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:43
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	16 Feb 2021 19:49:10

US3522299

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:36:58
User entered '1'	System	16 Feb 2021 19:49:10

US3522299

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:50
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4) (b) (4)	19 Mar 2021 11:50:21

US3522299

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:50
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered '19 Mar 2021'	(b) (4) Alandra White (b) (4) (b) (4)	19 Mar 2021 11:50:21

US3522299

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

[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 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:50
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered 'Clinic (Clinic)'	(b) (4) Alandra White (b) (4) (b) (4)	19 Mar 2021 11:50:21

US3522299

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
User entered 'VISIT4'	System	19 Mar 2021 11:50:21

US3522299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:56
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:16:28

US3522299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:56
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:16:28

US3522299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:56
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:16:28

US3522299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
User entered empty.	System	31 Mar 2021 15:16:28

US3522299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:56
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:16:28

US3522299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:56
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:16:28

US3522299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:56
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:16:28

US3522299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:56
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:16:28

US3522299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
User entered empty.	System	31 Mar 2021 15:16:28

US3522299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:56
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:16:28

US3522299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
User entered empty.	System	31 Mar 2021 15:16:28

US3522299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:56
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:16:28

US3522299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
User entered empty.	System	31 Mar 2021 15:16:28

US3522299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:56
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:16:28

US3522299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
User entered empty.	System	31 Mar 2021 15:16:28

US3522299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29

US3522299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29

US3522299

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:00
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4) (b) (4)	19 Mar 2021 11:54:08

US3522299

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:00
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered '19 Mar 2021'	(b) (4) Alandra White (b) (4) (b) (4)	19 Mar 2021 11:54:08

US3522299

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4) (b) (4)	19 Mar 2021 12:16:56

US3522299

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered '19 Mar 2021'	(b) (4) Alandra White (b) (4) (b) (4)	19 Mar 2021 12:16:56

US3522299

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered '08:12'	(b) (4) Alandra White (b) (4) (b) (4)	19 Mar 2021 12:16:56

US3522299

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
User entered '19 Mar 2021 08:12'	System	19 Mar 2021 12:16:56

US3522299

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:09
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4) (b) (4)	19 Mar 2021 12:17:02

US3522299

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:34:29
User entered 'I'	System	19 Mar 2021 12:17:02

US3522299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
	(b) (4)	
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	20 Apr 2021 16:05:41
	(b) (4)	

US3522299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
	(b) (4)	
User entered '20 Apr 2021'	Yaman Ahmed (b) (4)	20 Apr 2021 16:05:41
	(b) (4)	

US3522299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 16:05:41

US3522299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'RECOVERING WELL FROM OPEN VENTRAL HERNIA SURGERY. LAST FOLLOW-UP WITH PCP ON 16 APR 2021. POST-OP, DEVELOPED DEEP SOFT TISSUE INFECTION, PRESCRIBED 10-DAY COURSE OF CIPROFLOXACIN 500 MG' reason for change: Data Entry Error	(b) (4)	
User entered 'Recovering well from open ventral hernia surgery (24 Mar 2021), wound is healing well. Last follow-up with PCP on 16 Apr 2021. Post-op, developed a deep soft tissue infection, prescribed 10-day course of Ciprofloxacin 500 mg' (non-conformant).	Yaman Ahmed (b) (4)	20 Apr 2021 16:05:41

US3522299

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
	(b) (4)	
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	20 Apr 2021 16:06:29
	(b) (4)	

US3522299

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 16:06:29

US3522299

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

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:42:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4) (b) (4)	15 Jan 2021 14:42:54

US3522299

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

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:42:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered '15 Jan 2021'	(b) (4) Alandra White (b) (4) (b) (4)	15 Jan 2021 14:42:54

US3522299

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

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

[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 21:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:42:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Clinic (Clinic)'	(b) (4) Alandra White (b) (4) (b) (4)	15 Jan 2021 14:42:54

US3522299

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

Form: Visit Date

Generated On: 10 Jun 2021 07:59:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 14:42:54

US3522299

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:48

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered '15 Jan 2021'	(b) (4) Alandra White (b) (4) (b) (4)	15 Jan 2021 14:43:29

US3522299

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:48

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered '0'	(b) (4) Sharon Mathys (b) (4)	17 Mar 2021 12:53:00
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 06:26:11

US3522299

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:48

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4) (b) (4)	15 Jan 2021 14:43:29

US3522299

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:48

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered 'Amendment 6 or later (Amendment 6 or later)'	Sharon Mathys (b) (4)	17 Mar 2021 12:53:00
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:26:11

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:48

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered '15 Jan 2021'	(b) (4) Alandra White (b) (4) (b) (4)	15 Jan 2021 14:43:29

US3522299

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:48

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Alandra White (b) (4) (b) (4)	15 Jan 2021 14:43:29

US3522299

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:48

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	System	20 Jan 2021 08:13:36
User entered 'mRNA-1273 (mRNA-1273)'	Alandra White (b) (4)	15 Jan 2021 14:43:29
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:48

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	System	20 Jan 2021 08:13:36
User entered 'mRNA-1273 (mRNA-1273)'	Alandra White (b) (4)	15 Jan 2021 14:43:29
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:48

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'No (N)'	(b) (4) Alandra White (b) (4) (b) (4)	15 Jan 2021 14:43:29

US3522299

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:48

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User entered empty.	System	15 Jan 2021 14:43:29

US3522299

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:48

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User entered empty.	System	15 Jan 2021 14:43:29

US3522299

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:43:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4) (b) (4)	15 Jan 2021 14:43:52

US3522299

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:43:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered '15 Jan 2021'	(b) (4) Alandra White (b) (4) (b) (4)	15 Jan 2021 14:43:52

US3522299

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:43:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered '09:38'	(b) (4) Alandra White (b) (4) (b) (4)	15 Jan 2021 14:43:52

US3522299

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User entered '15 Jan 2021 09:38'	System	15 Jan 2021 14:43:52

US3522299

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:59:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:43:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4) (b) (4)	15 Jan 2021 14:44:11

US3522299

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:43:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered '15 Jan 2021'	(b) (4) Alandra White (b) (4) (b) (4)	15 Jan 2021 14:44:11

US3522299

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:43:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered '09:38'	(b) (4) Alandra White (b) (4) (b) (4)	15 Jan 2021 14:44:11

US3522299

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User entered '15 Jan 2021 09:38'	System	15 Jan 2021 14:44:11

US3522299

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:35
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 222 (31MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:45:41
Query 'Per DM CLR: Per Safety Follow Up Diary Day 222 (31MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'ae line 3 is what was reported' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	05 Apr 2021 19:36:40
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 222 (31MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 03:39:15
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:41
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:31:00
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:18:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 16:42:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 16:42:17
Data point term sent to Coder	System	25 Nov 2020 16:41:23
User entered 'hypertension'	(b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 May 2021 01:03:10
	(b) (4)	
DataPoint Un-verified.	Alandra White (b) (4)	30 Apr 2021 15:44:43
	(b) (4)	
Signature has been broken.	Alandra White (b) (4)	30 Apr 2021 15:44:43
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Alandra White (b) (4)	30 Apr 2021 15:44:43
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

None

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 May 2021 01:03:10
	(b) (4)	
Signature has been broken.	Alandra White (b) (4)	30 Apr 2021 16:28:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	25 Nov 2020 16:40:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:40:45

US3522299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 May 2021 01:03:10
DataPoint Un-verified.	(b) (4)	
	Alandra White (b) (4)	30 Apr 2021 15:44:43
	(b) (4)	
Signature has been broken.	Alandra White (b) (4)	30 Apr 2021 15:44:43
	(b) (4)	
User entered 'Per Unscheduled Communication 25-Nov-2020:	Alandra White (b) (4)	30 Apr 2021 15:44:43
Pt saw PCP 20 NOV 2020 and discovered BP of 160/112. Pt states her BP has been elevated in the past but was not high enough tot worry about. Was started on Amlodipine 5 mg daily. Pt states PCP wants her to continue taking this while awaiting some lab work and could possibly change medication following. Pt verbalized understanding and will reach out to study staff with any changes	(b) (4)	
Per Unscheduled Communication 16-Dec-2020:		
"Since the last update, my PCP has added another medication for my blood pressure. Losartan Potassium 25mg 1 tab per day was started on 12/10/2020."		
UPDATE 19 JAN 2021: BP IS IMPROVING (TODAY WAS IN 140S/80) AND WILL FOLLOW UP WITH PCP ON 22 JAN 2021' reason for change:		
New Information		
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
	(b) (4)	
User entered 'Update 19 Jan 2021: BP is improving (today was in 140s/80) and will follow up with PCP on 22 Jan 2021' reason for change: New Information	Yaman Ahmed (b) (4)	19 Jan 2021 17:30:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 16:40:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User entered '0'	System	25 Nov 2020 16:40:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User entered 'I'	System	25 Nov 2020 16:40:45

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:56
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:04
User entered 'USA-US131-2021-mRNA-1273-P301000014'	System	02 Apr 2021 14:57:00
User entered 'New'	(b) (4), (b) (6)	02 Apr 2021 14:57:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:58
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:17
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Hernias NEC, PT: Incarcerated hernia, LLT: Incarcerated hernia - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 10:44:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 10:44:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Data point term sent to Coder	(b) (4)	
User entered 'Ventral hernia with incarcerated small bowel'	System	01 Apr 2021 13:18:44
	(b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:00
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:04
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:07
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:58
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered '23 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:00
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:03
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 13:23:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 13:23:53
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:18:41
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered '25 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:59
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 May 2021 01:03:10
	(b) (4)	
DataPoint Un-verified.	Alandra White (b) (4)	30 Apr 2021 15:49:28
	(b) (4)	
Signature has been broken.	Alandra White (b) (4)	30 Apr 2021 15:49:28
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Alandra White (b) (4)	30 Apr 2021 15:49:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 16:30:00
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
	(b) (4), (b) (6)	
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:23:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 13:23:53
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 13:23:53
	(b) (4), (b) (6)	
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:18:41
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:18:41
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:03
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:18:41

US3522299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:05
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:08
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:09
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	01 Apr 2021 13:23:53
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		01 Apr 2021 13:23:53
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	01 Apr 2021 13:18:41
User entered '1'	(b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:12
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered '24 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 13:23:53
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:18:41

US3522299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:15
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered '26 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 13:23:53
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:18:41

US3522299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:19
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:20
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:27
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:32
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:34
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:36
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:39
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:41
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:45
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:51
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:30:59
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:18:41

US3522299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:19:46
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:02:44
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 16:01:34
User entered 'PARTICIPANT STARTED ABDOMINAL PAIN AND VOMITING ON 3/23 AND WENT TO ED ON 3/24. PARTICIPANT FOUND TO HAVE A VENTRAL HERNIA (CONFIRMED BY CT ON 24 MAR 2021 WHICH SHOWED OBSTRUCTING VENTRAL WALL HERNIA CAUSING SMALL BOWEL OBSTRUCTION) THAT WAS NOT REDUCIBLE. CBC ON 24 MAR 2021 SHOWED A SLIGHT INCREASE IN ABSOLUTE NEUTROPHILS (7.8 K/UL) AND DECREASE IN LYMPHOCYTES (1.00 K/UL). PATIENT TESTED NEGATIVE FOR COVID-19 ON 24 MAR 2021. PARTICIPANT HAD OPEN VENTRAL HERNIA REDUCTION WITH SUCCESSFUL REDUCTION AND HERNIA REPAIR ON 24 MAR 2021. Surgical peritoneal fluid and tissue were benign. PATIENT DISCHARGED ON 3/26 TO RECOVER AT HOME.' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 22:14:37
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'updated' (Site from Safety).	Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:54:37
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'updated' (Site from Safety).	Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:54:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Yaman Ahmed (b) (4)	20 Apr 2021 21:54:25
Signature has been broken.	(b) (4)	
	Yaman Ahmed (b) (4)	20 Apr 2021 21:54:25
	(b) (4)	
User entered 'PARTICIPANT STARTED ABDOMINAL PAIN AND VOMITING ON 3/23 AND WENT TO ED ON 3/24. PARTICIPANT FOUND TO HAVE A VENTRAL HERNIA (confirmed by CT on 24 Mar 2021 which showed obstructing ventral wall hernia causing small bowel obstruction) THAT WAS NOT REDUCIBLE. CBC on 24 Mar 2021 showed a slight increase in absolute neutrophils (7.8 k/uL) and decrease in lymphocytes (1.00 k/uL). Patient tested negative for covid-19 on 24 Mar 2021. PARTICIPANT HAD OPEN VENTRAL HERNIA REDUCTION WITH SUCCESSFUL REDUCTION AND HERNIA REPAIR on 24 Mar 2021. PATIENT DISCHARGED ON 3/26 TO RECOVER AT HOME.' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	20 Apr 2021 21:54:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:29
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:22
	(b) (4), (b) (6)	
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 16:38:37
	(b) (4), (b) (6)	
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 16:38:21
	(b) (4), (b) (6)	
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
	(b) (4)	
User entered 'Participant started abdominal pain and vomiting on 3/23 and went to ED on 3/24. participant found to have a ventral hernia that was not reducible. Participant had open ventral hernia reduction with successful reduction and hernia repair. Patient discharged on 3/26 to recover at home.'	(b) (4), (b) (6)	01 Apr 2021 13:18:41
	(b) (4), (b) (6)	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 13:18:41

US3522299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Apr 2021 13:18:41

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[AEID](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 19:06:30
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 19:06:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 May 2021 19:06:30
User signature succeeded.	Marcus Zervos (b) (4)	03 May 2021 15:49:15
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:43:13
Un-reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	03 May 2021 14:42:40
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 14:42:40
User entered 'USA-US131-2021-mRNA-1273-P301000014' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 14:42:40
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:41:54
User signature succeeded.	Marcus Zervos (b) (4)	01 May 2021 01:03:10
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:55:32
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 15:11:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please consider splitting event term to include ventral hernia and small bowel obstruction as CT scan revealed both.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 14:37:34
User closed query 'Unable to locate the grade and attribution of this event in the source.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 21:29:29
Query 'Unable to locate the grade and attribution of this event in the source.' answered with 'Ongoing and needs to be reviewed still. Not in scope of lock!' (Site from CRA).	Sharon Mathys (b) (4)	30 Apr 2021 21:13:41
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:56:37
Query 'PV Query: Please consider splitting event term to include ventral hernia and small bowel obstruction as CT scan revealed both.' answered with 'This AE refers to post-op wound complication' (Site from Safety).	Alandra White (b) (4)	30 Apr 2021 16:20:00
User opened query 'PV Query: Please consider splitting event term to include ventral hernia and small bowel obstruction as CT scan revealed both.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:08:13
User opened query 'Unable to locate the grade and attribution of this event in the source.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 12:50:47
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Wound infection bacterial, LLT: Wound infection bacterial - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 15:13:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 15:13:53
Data point term sent to Coder	System	20 Apr 2021 22:07:11
User entered 'Abdominal seroma-surgical wound(Pseudomonas aeruginosa and Proteus Mirabilis)'	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:56:44
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:56:46
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'No (N)'	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:56:50
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'No (N)'	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:56:59
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '5 Apr 2021'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:57:03
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 22:06:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:57:08
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:57:10
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:57:11
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 22:06:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Apr 2021 22:06:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Apr 2021 22:06:44
User entered 'No (N)' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:44
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Apr 2021 22:06:38
User entered empty.	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
	(b) (4)	
User entered '0'	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
	(b) (4)	
User entered '0'	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
	(b) (4)	
User entered '0'	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
	(b) (4)	
User entered '0'	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38
	(b) (4)	

US3522299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
	(b) (4)	
User entered '0'	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
	(b) (4)	
User entered '0'	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:57:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '0'	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:57:22
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'I'	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:57:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'I'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:57:26
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38

US3522299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:57:28
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:57:31
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Post-op, developed surgical wound abdominal seroma which was swabed for culture on 05 Ap 2021 and found to be infectious (Proteus Mirabilis and Pseudomonas aeruginosa), prescribed 10-day course of Ciprofloxacin 500 mg twice daily, taken from 12 Apr 2021 and ends 21 Apr 2021.'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:06:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 22:06:44

US3522299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 22:06:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:35
User closed query 'Please include the following medications for inpatient hospitalization from 24-26MAR2021: Amlodipine 24-26Mar2021; Nystatin 25-26Mar2021; Enoxaparin 25-26Mar2021; Bupivacaine 24Mar2021; Midazolam 24-25Mar2021.' (Site from CRA). Query 'Please include the following medications for inpatient hospitalization from 24-26MAR2021: Amlodipine 24-26Mar2021; Nystatin 25-26Mar2021; Enoxaparin 25-26Mar2021; Bupivacaine 24Mar2021; Midazolam 24-25Mar2021.' answered with 'these medications are present in record here' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 12:39:38
User opened query 'Please include the following medications for inpatient hospitalization from 24-26MAR2021: Amlodipine 24-26Mar2021; Nystatin 25-26Mar2021; Enoxaparin 25-26Mar2021; Bupivacaine 24Mar2021; Midazolam 24-25Mar2021.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 19:03:57
User opened query 'Please include the following medications for inpatient hospitalization from 24-26MAR2021: Amlodipine 24-26Mar2021; Nystatin 25-26Mar2021; Enoxaparin 25-26Mar2021; Bupivacaine 24Mar2021; Midazolam 24-25Mar2021.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:07:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:44:43
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4) (b) (4)	24 Aug 2020 12:09:45

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:40
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) (b) (4)	24 Aug 2020 16:00:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 16:00:39
Data point term sent to Coder	System	24 Aug 2020 12:12:27
User entered 'levothyroxine'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:11:32

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:40
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:11:32

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:40
User entered 'underactive thyroid'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:11:32

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
	(b) (4)	
Signature has been broken.	Alandra White (b) (4)	30 Apr 2021 15:53:04
	(b) (4)	
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	01 Apr 2021 13:46:12
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:09:40
User entered '50'	Alandra White (b) (4)	24 Aug 2020 12:11:32
	(b) (4)	

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:40
User entered 'ug (ug)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:11:32

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:40
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:11:32

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:40
User entered 'once daily (QD)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:11:32

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:40
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:11:32

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:40
User entered 'Oral (ORAL)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:11:32

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:40
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:11:32

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:40
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:11:32

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:40
User entered 'I'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:11:32

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:40
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:11:32

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:40
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:11:32

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:40
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:11:32

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 12:11:32

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 12:11:32

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 12:11:32

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 13:04:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 13:04:32
Data point term sent to Coder	System	24 Aug 2020 12:13:27
User entered 'doxycycline'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:12:56

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:42
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:12:56

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:42
User closed query 'Per DM CLR: Please note there is no Med History 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 Med History or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 09:27:14
Query 'Per DM CLR: Please note there is no Med History 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 Med History or AE eCRF. ' answered with 'added to Medical history ' (Site from DM).	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:00:44
User opened query 'Per DM CLR: Please note there is no Med History 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 Med History or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 13:04:13
User entered 'roscae'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:12:56

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:42
User entered '50-100' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	15 Jan 2021 14:49:49
User entered '100'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:12:56

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:42
User entered 'mg (mg)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:12:56

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:42
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:12:56

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:42
User entered 'once daily (QD)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:12:56

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:42
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:12:56

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:42
User entered 'Oral (ORAL)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:12:56

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:42
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:12:56

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:42
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:12:56

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:42
User entered 'I'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:12:56

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:42
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:12:56

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:42
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:12:56

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:42
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:12:56

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 12:12:56

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 12:12:56

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 12:12:56

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:44
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 12:16:44
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 12:16:44
Data point term sent to Coder	System	24 Aug 2020 12:15:32
User entered 'albuterol'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:14:50

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:44
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:14:50

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:44
User entered 'asthma'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:14:50

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:44
User entered '180'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:14:50

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:44
User entered 'ug (ug)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:14:50

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:44
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:14:50

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:44
User entered 'as needed (PRN)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:14:50

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:44
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:14:50

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:44
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:14:50

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:44
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:14:50

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:44
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:14:50

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:44
User entered 'I'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:14:50

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:44
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:14:50

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:44
User entered empty.	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:14:50

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:44
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	24 Aug 2020 12:14:50

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 12:14:50

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 12:14:50

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 12:14:50

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 19:16:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 19:16:45
Data point term sent to Coder	System	29 Sep 2020 19:16:11
User entered 'Tylenol'	Sharon Mathys (b) (4) (b) (4)	29 Sep 2020 19:15:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:09:51
User entered 'No (N)'	Sharon Mathys (b) (4)	29 Sep 2020 19:15:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:09:53
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. 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 or 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)	30 Nov 2020 08:39:14
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. 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 or 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 'Headache captured in eDiary for day 1 post vaccination ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 16:26:15

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:10:10
User entered '650'	Sharon Mathys (b) (4) (b) (4)	29 Sep 2020 19:15:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:10:12
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	29 Sep 2020 19:15:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:10:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	29 Sep 2020 19:15:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:10:20
User entered 'once (ONCE)'	Sharon Mathys (b) (4) (b) (4)	29 Sep 2020 19:15:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:10:25
User entered empty.	Sharon Mathys (b) (4) (b) (4)	29 Sep 2020 19:15:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:10:27
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	29 Sep 2020 19:15:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:10:29
User entered empty.	Sharon Mathys (b) (4) (b) (4)	29 Sep 2020 19:15:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:10:35
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	29 Sep 2020 19:15:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:10:39
User entered '0'	Sharon Mathys (b) (4)	29 Sep 2020 19:15:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:10:40
User entered 'No (N)'	Sharon Mathys (b) (4)	29 Sep 2020 19:15:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:31:03
User closed query 'Per eDiary review, medication was also taken on 22Sep2020 (Day 2 of eDiary). Please kindly confirm if date should be amended.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:31:01
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
Query 'Per eDiary review, medication was also taken on 22Sep2020 (Day 2 of eDiary). Please kindly confirm if date should be amended.' answered with 'diary states " No interference with activity" for day two. Did not take medications. This date is accurate per diary' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 19:34:02
User opened query 'Per eDiary review, medication was also taken on 22Sep2020 (Day 2 of eDiary). Please kindly confirm if date should be amended.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:09:27
User entered '21 Sep 2020'	Sharon Mathys (b) (4)	29 Sep 2020 19:15:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:10:44
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	29 Sep 2020 19:15:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:15
User entered empty.	System	29 Sep 2020 19:15:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:15
User entered empty.	System	29 Sep 2020 19:15:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:15
User entered empty.	System	29 Sep 2020 19:15:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:17:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 15:38:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 15:38:29
Data point term sent to Coder	System	02 Feb 2021 15:38:16
Coding entries removed.	Alayna Wilder (b) (4) (b) (4)	02 Feb 2021 15:37:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:53:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:53:53
Data point term sent to Coder	System	15 Jan 2021 14:53:27
Coding entries removed.	Alandra White (b) (4) (b) (4)	15 Jan 2021 14:53:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:51:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:51:52
Data point term sent to Coder	System	15 Jan 2021 14:51:25
Coding entries removed.	Alandra White (b) (4) (b) (4)	15 Jan 2021 14:51:21

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 14:14:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 14:14:53
Data point term sent to Coder	System	06 Oct 2020 14:11:17
User entered 'Tylenol'	Kristin Eis (b) (4)	06 Oct 2020 14:10:27

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:18:02
User entered 'No (N)'	Kristin Eis (b) (4)	06 Oct 2020 14:10:27

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:30
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication of PAIN IN LOWER EXTREMITIES during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 09:02:10
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication of PAIN IN LOWER EXTREMITIES during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'see update and correlating medical dx' (Site from DM).	Alayna Wilder (b) (4) (b) (4)	02 Feb 2021 15:37:45
User entered 'pain due to swelling in lower bilateral extremities' reason for change: Data Entry Error	Alayna Wilder (b) (4) (b) (4)	02 Feb 2021 15:37:32
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication of PAIN IN LOWER EXTREMITIES during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:04:18
User entered 'HEADACHE OR PAIN in lower extremities' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	15 Jan 2021 14:53:05
User entered 'HEADACHE Or pain' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	15 Jan 2021 14:51:21
User entered 'HEADACHE'	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:10:27

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:20:55
User entered '500' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 19:15:32
User entered '550'	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:10:27

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:20:57
User entered 'mg (mg)'	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:10:27

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:20:59
User entered empty.	Kristin Eis (b) (4)	06 Oct 2020 14:10:27

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:21:02
User entered 'as needed (PRN)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 19:15:32
User entered 'twice daily (BID)'	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:10:27

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:21:03
User entered empty.	Kristin Eis (b) (4)	06 Oct 2020 14:10:27

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:21:19
User entered 'Oral (ORAL)'	Kristin Eis (b) (4)	06 Oct 2020 14:10:27

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:21:24
User entered empty.	Kristin Eis (b) (4)	06 Oct 2020 14:10:27

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:21:30
User entered '29 Sep 2020'	Kristin Eis (b) (4)	06 Oct 2020 14:10:27

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:23:42
User entered '0'	Kristin Eis (b) (4)	06 Oct 2020 14:10:27

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:20
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:31:26
User closed query 'Per review of source for Safety call Day 50, that was the last time them ild headache that started on 29Sep2020 was mentioned in the source. Please advise if condition is still ongoing or if this has resolved. Please provide date of resolution.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:31:24
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
Query 'Per review of source for Safety call Day 50, that was the last time them ild headache that started on 29Sep2020 was mentioned in the source. Please advise if condition is still ongoing or if this has resolved. Please provide date of resolution.' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:36:05
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	09 Mar 2021 19:35:54
User opened query 'Per review of source for Safety call Day 50, that was the last time them ild headache that started on 29Sep2020 was mentioned in the source. Please advise if condition is still ongoing or if this has resolved. Please provide date of resolution.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:17:55
User closed query 'Per DM CLR Requery: Previous response noted. However, there is still no AE that matches this Con Med indication of PAIN IN LOWER EXTREMITIES during this time frame. Either add the medical condition " PAIN IN LOWER EXTREMITIES" in AE ecrf or provide stop date.. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 09:02:37

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR Requery: Previous response noted. However, there is still no AE that matches this Con Med indication of PAIN IN LOWER EXTREMITIES during this time frame. Either add the medical condition " PAIN IN LOWER EXTREMITIES" in AE ecrf or provide stop date.. Otherwise, provide clarification for continued use of medication.' answered with 'See update and correlating medical dx' (Site from DM).	Alayna Wilder (b) (4) (b) (4)	02 Feb 2021 15:38:00
User opened query 'Per DM CLR Requery: Previous response noted. However, there is still no AE that matches this Con Med indication of PAIN IN LOWER EXTREMITIES during this time frame. Either add the medical condition " PAIN IN LOWER EXTREMITIES" in AE ecrf or provide stop date.. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:10:26
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 07:06:11
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated, also takes for pain in lower extremities ' (Site from DM).	Alandra White (b) (4) (b) (4)	15 Jan 2021 14:54:51
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 02:31:52
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:10:27

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:23:52
User entered 'No (N)' reason for change: Data Entry Error	Kristin Eis (b) (4)	06 Oct 2020 14:10:31
User entered 'Yes (Y)'	(b) (4) Kristin Eis (b) (4) (b) (4)	06 Oct 2020 14:10:27

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:20
User entered empty.	System	12 Oct 2020 19:15:32
User entered '2'	System	06 Oct 2020 14:10:27

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:20
User entered empty.	System	12 Oct 2020 19:15:32
User entered '1'	System	06 Oct 2020 14:10:27

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:20
User entered empty.	System	12 Oct 2020 19:15:32
User entered '804 (804)'	System	06 Oct 2020 14:10:27

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE INACT SPLIT 4V, PRODUCTSYNONYM: QUADRIVALENT INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 05:56:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 05:56:41
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:24
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL AND VIRAL VACCINES, COMBINED, ATC: BACTERIAL AND VIRAL VACCINES, COMBINED, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE;POLIO VACCINE;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: QUAD VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 19:20:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 19:20:27
Data point term sent to Coder	System	12 Oct 2020 19:19:39
User entered 'Influenza quad vaccine'	(b) (4), (b) (6)	12 Oct 2020 19:19:17

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:26
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 19:19:17

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:26
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:24:24
User entered 'Prevention of influenza'	(b) (4), (b) (6)	12 Oct 2020 19:19:17

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:26
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:24
User entered '0.5'	(b) (4), (b) (6)	12 Oct 2020 19:19:17

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:26
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:24:24
User entered 'mL (mL)'	(b) (4), (b) (6)	12 Oct 2020 19:19:17

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:26
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:24
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 19:19:17

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:26
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:24:24
User entered 'once (ONCE)'	(b) (4), (b) (6)	12 Oct 2020 19:19:17

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:26
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:24:24
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 19:19:17

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:26
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:24
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	12 Oct 2020 19:19:17

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:26
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:24
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 19:19:17

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:26
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:24
User entered '9 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 19:19:17

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:26
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:24
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 19:19:17

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:26
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:24
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 19:19:17

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:26
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:24
User entered '9 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 19:19:17

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:26
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:24:24
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 19:19:17

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:26
User entered empty.	System	12 Oct 2020 19:19:17

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:26
User entered empty.	System	12 Oct 2020 19:19:17

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:26
User entered empty.	System	12 Oct 2020 19:19:17

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:24:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 18:38:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 18:38:37
Data point term sent to Coder	System	21 Oct 2020 18:37:15
User entered 'Tylenol'	(b) (4), (b) (6)	21 Oct 2020 18:36:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:24:36
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 18:36:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:24:36
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)	21 Jan 2021 10:24:02
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 'Headache did not meet AE reporting criteria, was recorded in ed diary' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 14:01:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

[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).	(b) (4), (b) (6)	20 Jan 2021 11:21:56
User entered 'Headache'	(b) (4), (b) (6)	21 Oct 2020 18:36:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:36
User entered '1300'	(b) (4), (b) (6)	21 Oct 2020 18:36:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:36
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Oct 2020 18:36:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:36
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 18:36:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:36
User entered 'once (ONCE)'	(b) (4), (b) (6)	21 Oct 2020 18:36:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:24:36
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 18:36:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:24:36
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Oct 2020 18:36:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:24:36
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 18:36:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:24:36
User entered '24 Aug 2020'	(b) (4), (b) (6)	21 Oct 2020 18:36:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:36
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 18:36:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:24:36
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 18:36:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:24:36
User entered '24 Aug 2020'	(b) (4), (b) (6)	21 Oct 2020 18:36:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:24:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 18:36:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:32
User entered empty.	System	21 Oct 2020 18:36:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:32
User entered empty.	System	21 Oct 2020 18:36:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:32
User entered empty.	System	21 Oct 2020 18:36:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:47
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Nov 2020 16:41:15
User coded data point as Term Coded data point by	Coder Import (b) (4)	25 Nov 2020 16:41:15
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	25 Nov 2020 16:40:22
User entered 'Amlodipine'	(b) (4), (b) (6)	25 Nov 2020 16:39:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:48
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'No (N)'	(b) (4), (b) (6)	25 Nov 2020 16:39:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'hypertension'	(b) (4), (b) (6)	25 Nov 2020 16:39:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:51
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered '5'	(b) (4), (b) (6)	25 Nov 2020 16:39:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Nov 2020 16:39:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:11
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 16:39:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:12
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:39:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:14
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:39:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:16
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Nov 2020 16:39:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:17
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 16:39:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:39:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 16:39:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:47:57
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
Signature has been broken.	(b) (4)	
	Alandra White (b) (4)	19 Mar 2021 12:21:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	19 Mar 2021 12:21:12
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 16:39:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:47:59
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
Signature has been broken.	(b) (4) Alandra White (b) (4)	19 Mar 2021 12:21:12
User entered '15 Feb 2021' reason for change: Data Entry Error	(b) (4) Alandra White (b) (4)	19 Mar 2021 12:21:12
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:39:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:23
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 05:04:24
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	26 Jan 2021 18:01:09
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Jan 2021 18:01:00
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 10:44:05

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 16:39:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:37
User entered '1'	System	25 Nov 2020 16:39:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:37
User entered '1'	System	25 Nov 2020 16:39:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:37
User entered '804 (804)'	System	25 Nov 2020 16:39:55

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:48
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN POTASSIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Dec 2020 12:22:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 12:22:56
Data point term sent to Coder	System	16 Dec 2020 12:21:42
User entered 'Losartan Potassium'	Sharon Mathys (b) (4) (b) (4)	16 Dec 2020 12:21:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	16 Dec 2020 12:21:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:51
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'Hypertension'	(b) (4) Sharon Mathys (b) (4) (b) (4)	16 Dec 2020 12:21:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered '25'	(b) (4) Sharon Mathys (b) (4) (b) (4)	16 Dec 2020 12:21:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:57
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'mg (mg)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	16 Dec 2020 12:21:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:58
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	16 Dec 2020 12:21:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:00
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'once daily (QD)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	16 Dec 2020 12:21:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:02
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	16 Dec 2020 12:21:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:03
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'Oral (ORAL)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	16 Dec 2020 12:21:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:04
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	16 Dec 2020 12:21:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:05
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered '10 Dec 2020'	(b) (4) Sharon Mathys (b) (4) (b) (4)	16 Dec 2020 12:21:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	16 Dec 2020 12:21:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:48:31
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Alandra White (b) (4)	15 Jan 2021 15:03:13
User entered 'Yes (Y)'	(b) (4)	
	Sharon Mathys (b) (4)	16 Dec 2020 12:21:08
	(b) (4)	

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:48:33
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Alandra White (b) (4)	15 Jan 2021 15:03:13
User entered empty.	(b) (4)	
	Sharon Mathys (b) (4)	16 Dec 2020 12:21:08
	(b) (4)	

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:10
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	16 Dec 2020 12:21:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:41
User entered '1'	System	16 Dec 2020 12:21:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:41
User entered '1'	System	16 Dec 2020 12:21:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:23:41
User entered '804 (804)'	System	16 Dec 2020 12:21:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:44:43
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 15:18:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 15:18:52
Data point term sent to Coder User entered 'losartan'	System Alandra White (b) (4)	15 Jan 2021 15:02:30 15 Jan 2021 15:02:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:44:43
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'No (N)'	(b) (4) Alandra White (b) (4)	15 Jan 2021 15:02:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:44:43
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'Hypertension'	(b) (4) Alandra White (b) (4)	15 Jan 2021 15:02:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:44:43
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered '100'	(b) (4) Alandra White (b) (4)	15 Jan 2021 15:02:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:44:43
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'mg (mg)'	(b) (4) Alandra White (b) (4)	15 Jan 2021 15:02:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:44:43
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4) Alandra White (b) (4)	15 Jan 2021 15:02:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:44:43
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'once daily (QD)'	(b) (4) Alandra White (b) (4)	15 Jan 2021 15:02:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:44:43
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4) Alandra White (b) (4)	15 Jan 2021 15:02:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:44:43
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'Oral (ORAL)'	(b) (4) Alandra White (b) (4)	15 Jan 2021 15:02:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:44:43
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4) Alandra White (b) (4)	15 Jan 2021 15:02:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:44:43
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered '12 Jan 2021'	(b) (4) Alandra White (b) (4)	15 Jan 2021 15:02:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:44:43
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered '0'	(b) (4) Alandra White (b) (4)	15 Jan 2021 15:02:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:44:43
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	15 Jan 2021 15:02:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:44:43
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered empty.	(b) (4) Alandra White (b) (4)	15 Jan 2021 15:02:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:44:43
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:21:58
User entered 'No (N)'	(b) (4) Alandra White (b) (4)	15 Jan 2021 15:02:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 15:02:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 15:02:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Jan 2021 15:02:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:45:17
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 12:20:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	19 Mar 2021 12:20:32
Data point term sent to Coder	System	19 Mar 2021 12:20:02
User entered 'amlodipine'	Alandra White (b) (4)	19 Mar 2021 12:19:54
	(b) (4)	

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:45:17
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered 'No (N)'	(b) (4) Alandra White (b) (4)	19 Mar 2021 12:19:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:45:17
User closed query 'Per DM CLR: Was the frequency of this medication increased because the patient experienced a worsening or exacerbation of the medical condition being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for an increased dose of this medication.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 04:11:59
Query 'Per DM CLR: Was the frequency of this medication increased because the patient experienced a worsening or exacerbation of the medical condition being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for an increased dose of this medication.' answered with 'No, participant's PCP is actively titrating meds to find correct dosing. Hypertension has not worsened. See previous REDCap note regarding hypertension medications. ' (Site from DM).	Alandra White (b) (4)	07 Apr 2021 17:25:22
User opened query 'Per DM CLR: Was the frequency of this medication increased because the patient experienced a worsening or exacerbation of the medical condition being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for an increased dose of this medication.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 07:18:54
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered 'hypertension'	Alandra White (b) (4)	19 Mar 2021 12:19:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:45:17
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered '5'	(b) (4) Alandra White (b) (4)	19 Mar 2021 12:19:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:45:17
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered 'mg (mg)'	(b) (4) Alandra White (b) (4)	19 Mar 2021 12:19:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:45:17
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered empty.	(b) (4) Alandra White (b) (4)	19 Mar 2021 12:19:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:45:17
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered 'twice daily (BID)'	(b) (4) Alandra White (b) (4)	19 Mar 2021 12:19:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:45:17
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered empty.	(b) (4) Alandra White (b) (4)	19 Mar 2021 12:19:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:45:17
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered 'Oral (ORAL)'	(b) (4) Alandra White (b) (4)	19 Mar 2021 12:19:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:45:17
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered empty.	(b) (4) Alandra White (b) (4)	19 Mar 2021 12:19:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:45:17
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered '15 Feb 2021'	(b) (4) Alandra White (b) (4)	19 Mar 2021 12:19:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:45:17
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered '0'	(b) (4) Alandra White (b) (4)	19 Mar 2021 12:19:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:45:17
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	19 Mar 2021 12:19:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:45:17
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered empty.	(b) (4) Alandra White (b) (4)	19 Mar 2021 12:19:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:45:17
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:13
User entered 'No (N)'	(b) (4) Alandra White (b) (4)	19 Mar 2021 12:19:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Mar 2021 12:19:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Mar 2021 12:19:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Mar 2021 12:19:54

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:51
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL, PRODUCTS YNOMY: POLYETHYLENE GLYCOL [MACROGOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 11:00:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 11:00:50
Data point term sent to Coder	System	01 Apr 2021 13:31:01
User entered 'Polyethylene glycol'	(b) (4), (b) (6)	01 Apr 2021 13:30:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:51
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:30:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:51
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'ventral hernia surgery'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:30:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:51
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '17'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:30:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:51
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:30:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:51
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:30:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:51
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:30:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:51
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:30:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:51
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:30:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:51
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:30:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:51
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:30:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:51
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:30:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:51
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:30:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:51
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:30:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:51
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:30:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 13:30:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 13:30:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 13:30:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Apr 2021 14:45:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 14:45:29
Data point term sent to Coder	System	01 Apr 2021 13:32:02
User entered 'Tramadol'	(b) (4), (b) (6)	01 Apr 2021 13:31:33

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:31:33

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'post surgical pain'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:31:33

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '50'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:31:33

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:31:33

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:59:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:31:33

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	01 Apr 2021 13:31:51
User entered 'other (OTHER)' reason for change:	(b) (4), (b) (6)	01 Apr 2021 13:31:51
Data Entry Error		
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	01 Apr 2021 13:31:33
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	01 Apr 2021 13:31:33

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:59:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'prn q6'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:31:33

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:31:33

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:31:33

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:59:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:31:33

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:31:33

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:31:33

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:31:33

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:31:33

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 13:31:33

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 13:31:33

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 13:31:33

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Apr 2021 14:26:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 14:26:28
Data point term sent to Coder	System	01 Apr 2021 13:40:07
User entered 'Morphine'	(b) (4), (b) (6)	01 Apr 2021 13:39:43

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 13:39:43

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'ventral hernia pain'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:39:43

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '4'	(b) (4), (b) (6)	01 Apr 2021 13:39:43

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Apr 2021 13:39:43

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:59:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:39:43

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Apr 2021 13:39:43

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:39:43

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	01 Apr 2021 13:39:43

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:39:43

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '24 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 13:39:43

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 13:39:43

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 13:40:55
User entered 'No (N)' reason for change: Data Entry Error	System	01 Apr 2021 13:40:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 13:39:43
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:39:43

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:59:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '24 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 13:39:43

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:39:43

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
User entered empty.	System	01 Apr 2021 13:39:43

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
User entered empty.	System	01 Apr 2021 13:39:43

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
User entered empty.	System	01 Apr 2021 13:39:43

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:42
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Apr 2021 13:42:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 13:42:05
Data point term sent to Coder	System	01 Apr 2021 13:41:08
User entered 'Dilaudid'	(b) (4), (b) (6)	01 Apr 2021 13:40:46

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:42
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:40:46

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:42
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'Post surgical pain'	(b) (4), (b) (6)	01 Apr 2021 13:40:46

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:42
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '0.5'	(b) (4), (b) (6)	01 Apr 2021 13:40:46

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:42
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Apr 2021 13:40:46

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:59:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:42
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:40:46

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:47
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:34:49
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
DataPoint Un-verified.	(b) (4)	
	Yaman Ahmed (b) (4)	20 Apr 2021 16:27:44
Signature has been broken.	(b) (4)	
	Yaman Ahmed (b) (4)	20 Apr 2021 16:27:44
User entered 'once daily (QD)' reason for change:	(b) (4)	
Data Entry Error	Yaman Ahmed (b) (4)	20 Apr 2021 16:27:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 19:50:42
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
	(b) (4)	
User entered 'once (ONCE)'	(b) (4), (b) (6)	01 Apr 2021 13:40:46

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:42
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:40:46

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:42
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	01 Apr 2021 13:40:46

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:59:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:42
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:40:46

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:59:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:47
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User closed query 'This medication was also taken on 24MAR2021 per ED Medications list. Please update start date.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:55:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:55:09
Query 'This medication was also taken on 24MAR2021 per ED Medications list. Please update start date.' answered with 'corrected' (Site from CRA).	Yaman Ahmed (b) (4)	20 Apr 2021 16:27:52
Signature has been broken.	Yaman Ahmed (b) (4)	20 Apr 2021 16:27:44
User entered '24 Mar 2021' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	20 Apr 2021 16:27:44
User opened query 'This medication was also taken on 24MAR2021 per ED Medications list. Please update start date.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:52:17
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:42
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '25 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 13:40:46

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:42
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 13:40:46

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:42
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:40:46

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:59:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:42
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:40:46

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:42
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 13:40:46

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:47
User entered '1'	System	20 Apr 2021 16:27:44
User entered empty.	System	01 Apr 2021 13:40:46

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:47
User entered '1'	System	20 Apr 2021 16:27:44
User entered empty.	System	01 Apr 2021 13:40:46

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:47
User entered '804 (804)'	System	20 Apr 2021 16:27:44
User entered empty.	System	01 Apr 2021 13:40:46

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
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.	(b) (4) Coder Import (b) (4) (b) (4)	05 Apr 2021 09:32:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:32:21
Data point term sent to Coder	System	01 Apr 2021 13:43:11
User entered 'Ondansetron'	(b) (4), (b) (6)	01 Apr 2021 13:42:25

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 13:42:25

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'nausea related to ventral hernia'	(b) (4), (b) (6)	01 Apr 2021 13:42:25

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '4'	(b) (4), (b) (6)	01 Apr 2021 13:42:25

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Apr 2021 13:42:25

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:59:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:42:25

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:42:25

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:59:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'twice as needed'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:42:25

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	01 Apr 2021 13:42:25

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:42:25

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '24 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 13:42:25

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 13:42:25

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:42:25

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:59:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:42:25

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:55:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:42:25

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:54
User entered empty.	System	01 Apr 2021 13:42:25

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:54
User entered empty.	System	01 Apr 2021 13:42:25

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:54
User entered empty.	System	01 Apr 2021 13:42:25

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: CITRIC ACID;SODIUM CITRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 07:25:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:25:50
Data point term sent to Coder	System	01 Apr 2021 13:44:12
User entered 'Citric acid sodium citrate'	(b) (4), (b) (6)	01 Apr 2021 13:43:24

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:43:24

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'nauseas from ventral hernia'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:43:24

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '30'	(b) (4), (b) (6)	01 Apr 2021 13:43:24

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'mL (mL)'	(b) (4), (b) (6)	01 Apr 2021 13:43:24

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:59:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:43:24

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:43:24

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:43:24

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Apr 2021 13:43:24

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:43:24

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '24 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 13:43:24

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 13:43:24

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 13:43:24

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:59:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '24 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 13:43:24

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:43:24

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
User entered empty.	System	01 Apr 2021 13:43:24

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
User entered empty.	System	01 Apr 2021 13:43:24

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:58
User entered empty.	System	01 Apr 2021 13:43:24

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Apr 2021 09:55:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:55:59
Data point term sent to Coder	System	01 Apr 2021 13:45:13
User entered 'famotidine'	(b) (4), (b) (6)	01 Apr 2021 13:44:12

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 13:44:12

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'nausea from ventral hernia'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:44:12

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '20'	(b) (4), (b) (6)	01 Apr 2021 13:44:12

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Apr 2021 13:44:12

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:59:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:44:12

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:44:12

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:44:12

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:44:12

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:44:12

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:44:12

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:44:12

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:44:12

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:44:12

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:25
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 13:44:12

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:10
User entered empty.	System	01 Apr 2021 13:44:12

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:10
User entered empty.	System	01 Apr 2021 13:44:12

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:10
User entered empty.	System	01 Apr 2021 13:44:12

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Apr 2021 09:22:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:22:52
Data point term sent to Coder	System	01 Apr 2021 13:45:13
User entered 'Cefazolin'	(b) (4), (b) (6)	01 Apr 2021 13:44:52

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:44:52

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'Pre surgical prophylaxis'	(b) (4), (b) (6)	01 Apr 2021 13:44:52

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '2'	(b) (4), (b) (6)	01 Apr 2021 13:44:52

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:44:52

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:59:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:44:52

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:44:52

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:44:52

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	01 Apr 2021 13:44:52

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:44:52

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:59:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:44:52

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:44:52

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	01 Apr 2021 13:46:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 13:46:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 13:46:21
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:44:52
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:44:52

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '24 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 13:44:52

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 13:44:52

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:15
User entered empty.	System	01 Apr 2021 13:44:52

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:15
User entered empty.	System	01 Apr 2021 13:44:52

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:26:15
User entered empty.	System	01 Apr 2021 13:44:52

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:37:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:37:55
Data point term sent to Coder	System	01 Apr 2021 13:48:15
User entered 'hydrocodone-acetaminophen'	(b) (4), (b) (6)	01 Apr 2021 13:48:14

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:48:14

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'post surgical pain'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:48:14

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '5-325'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:48:14

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Apr 2021 13:48:14

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:59:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:48:14

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:48:14

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'prn q6'	(b) (4), (b) (6)	01 Apr 2021 13:48:14

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Apr 2021 13:48:14

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:48:14

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '24 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 13:48:14

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 13:48:14

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:48:14

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '25 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 13:48:14

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 13:48:14

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:35
User entered empty.	System	01 Apr 2021 13:48:14

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:35
User entered empty.	System	01 Apr 2021 13:48:14

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:35
User entered empty.	System	01 Apr 2021 13:48:14

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Apr 2021 14:22:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 14:22:48
Data point term sent to Coder	System	01 Apr 2021 13:49:16
User entered 'Methocarbamol'	(b) (4), (b) (6)	01 Apr 2021 13:49:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 13:49:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'post surgical pain'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:49:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '1000'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:49:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Apr 2021 13:49:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:59:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:49:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:49:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:49:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	01 Apr 2021 13:49:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:49:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:49:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 13:49:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:49:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '24 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 13:49:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 13:49:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User entered empty.	System	01 Apr 2021 13:49:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User entered empty.	System	01 Apr 2021 13:49:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User entered empty.	System	01 Apr 2021 13:49:06

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:17:24
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 13:53:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 13:53:28
Data point term sent to Coder	System	01 Apr 2021 13:52:18
User entered 'Acetaminophen'	(b) (4), (b) (6)	01 Apr 2021 13:51:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:17:24
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 13:51:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:17:24
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'post surgical pain'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:51:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:17:24
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '1000'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:51:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:17:24
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Apr 2021 13:51:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:59:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:17:24
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:51:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:17:24
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:51:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:17:24
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'q6'	(b) (4), (b) (6)	01 Apr 2021 13:51:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:17:24
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	01 Apr 2021 13:51:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:17:24
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:51:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:17:24
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '25 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 13:51:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:17:24
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 13:51:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:17:24
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 13:51:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:59:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:17:24
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered '26 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 13:51:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:17:24
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:51:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:46
User entered empty.	System	01 Apr 2021 13:51:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:46
User entered empty.	System	01 Apr 2021 13:51:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:46
User entered empty.	System	01 Apr 2021 13:51:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:59:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Apr 2021 06:15:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 06:15:04
Data point term sent to Coder	System	20 Apr 2021 20:45:05
User entered 'bupivacaine 0.5%'	Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:44:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:44:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'ventral hernia surgery'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:44:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '30'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:44:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'mL (mL)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:44:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:59:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:44:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'once (ONCE)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:44:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:44:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Other (OTHER)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:44:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'local infiltration'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:44:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '24 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:44:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '0'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:44:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:44:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '24 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:44:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:44:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User entered empty.	System	20 Apr 2021 20:44:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User entered empty.	System	20 Apr 2021 20:44:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User entered empty.	System	20 Apr 2021 20:44:08

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:02
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 21:31:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:31:37
Data point term sent to Coder	System	20 Apr 2021 20:54:16
User entered 'midazolam'	Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:53:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:02
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:53:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:02
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'sedation for ventral hernia surgery'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:53:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:02
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'l'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:53:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:02
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'mg (mg)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:53:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:59:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:02
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:53:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:02
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'other (OTHER)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:53:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:59:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:02
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'at 5 minute or 1 minute intervals as needed for a maximum dose of 4 mg'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:53:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:02
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:53:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:02
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:53:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:02
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '24 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:53:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:02
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '0'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:53:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:02
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:53:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:02
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:37
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:36:34
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 19:03:04
User entered '25 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 19:03:04
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '24 Mar 2021'	Yaman Ahmed (b) (4)	20 Apr 2021 20:53:40
	(b) (4)	

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:02
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:53:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:02
User entered empty.	System	20 Apr 2021 20:53:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:02
User entered empty.	System	20 Apr 2021 20:53:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:02
User entered empty.	System	20 Apr 2021 20:53:40

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:16
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 20:57:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:57:41
Data point term sent to Coder	System	20 Apr 2021 20:56:25
User entered 'enoxaparin'	Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:56:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:16
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:56:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:16
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'DVT prophylaxis'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:56:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:16
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '40'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:56:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:16
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'mg (mg)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:56:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:59:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:16
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:56:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:16
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'once daily (QD)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:56:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:16
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:56:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:16
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:56:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:16
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:56:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:16
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '25 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:56:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:16
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '0'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:56:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:16
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:56:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:16
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '26 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:56:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:16
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 20:56:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:16
User entered '1'	System	20 Apr 2021 20:56:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:16
User entered '1'	System	20 Apr 2021 20:56:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:16
User entered '804 (804)'	System	20 Apr 2021 20:56:20

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:55
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: ANTIBIOTICS, PRODUCT: NYSTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Apr 2021 06:48:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 06:48:52
Data point term sent to Coder	System	20 Apr 2021 21:02:39
User entered 'Nystatin topical powder'	Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:02:13

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:55
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:02:13

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:55
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'antifungal prophylaxis of groin region'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:02:13

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:55
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '100,000'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:02:13

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:55
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Other (OTHER)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:02:13

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 07:59:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:55
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'unit/gram'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:02:13

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:55
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'other (OTHER)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:02:13

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:55
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'twice on 25 Mar 2021 and once on 26 Mar 2021'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 21:02:13

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:55
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Topical (TOPICAL)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:02:13

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 07:59:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:55
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:02:13

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:55
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '25 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:02:13

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:55
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '0'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:02:13

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:55
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:02:13

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 07:59:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:55
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '26 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:02:13

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:22
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:41:55
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:02:13

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:22
User entered empty.	System	20 Apr 2021 21:02:13

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:22
User entered empty.	System	20 Apr 2021 21:02:13

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:22
User entered empty.	System	20 Apr 2021 21:02:13

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:42:04
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 21:43:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 21:43:38
Data point term sent to Coder	System	20 Apr 2021 21:42:45
User entered 'Amlodipine'	Yaman Ahmed (b) (4)	20 Apr 2021 21:42:15

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:42:04
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 21:42:15

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:42:04
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'hypertension'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 21:42:15

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:44
User closed query 'Per source this was 10mg' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:55:39
Query 'Per source this was 10mg' answered with 'Per source (Visit 3 and even note) while dose is 10 mg tablet, they are instructed to take 5 mg by mouth twice daily. So per administration, it is 5 mg as has been documented by site staff' (Site from CRA).	Sharon Mathys (b) (4)	28 Apr 2021 12:33:18
User opened query 'Per source this was 10mg' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 12:51:53
	(b) (4), (b) (6)	27 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:42:04
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '5'	(b) (4)	
	Yaman Ahmed (b) (4)	20 Apr 2021 21:42:15
	(b) (4)	

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:42:04
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'mg (mg)'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 21:42:15

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:59:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:42:04
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 21:42:15

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:42:04
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'twice daily (BID)'	Yaman Ahmed (b) (4)	20 Apr 2021 21:42:15

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:59:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:42:04
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 21:42:15

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:42:04
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Oral (ORAL)'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 21:42:15

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:42:04
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 21:42:15

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:59:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:56:09
User closed query 'Although there is an ongoing medication for Amlodipine from 15Feb2021, Subject was given 10mg on 24-26Mar2021. Please review and update.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:56:07
Query 'Although there is an ongoing medication for Amlodipine from 15Feb2021, Subject was given 10mg on 24-26Mar2021. Please review and update.' answered with 'The tablet size is 10 mg. Subject is taking 5 mg (half tablet) twice daily. So dosage per administration is 5 mg. This is reflected in Visit 3 note and notes from 24-26 mar 2021' (Site from CRA).	Sharon Mathys (b) (4) (b) (4)	28 Apr 2021 12:34:13
User opened query 'Although there is an ongoing medication for Amlodipine from 15Feb2021, Subject was given 10mg on 24-26Mar2021. Please review and update.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 12:52:47
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 12:45:01
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:42:04
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:12:14
User entered '15 Feb 2021'	Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:42:15

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:56:13
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 12:45:04
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:42:04
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '0'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:42:15

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:56:15
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 12:45:07
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:42:04
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 21:42:15
	(b) (4)	

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:56:17
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 12:45:09
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:42:04
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 21:42:15

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:42:04
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 21:42:15

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Apr 2021 21:42:15

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 21:42:15

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 21:42:15

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:59:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:56:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 06:21:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 06:21:48
Data point term sent to Coder	System	20 Apr 2021 22:11:14
User entered 'ciprofloxacin'	Yaman Ahmed (b) (4)	20 Apr 2021 22:10:35

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:59:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:56:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:10:35

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:56:27
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'post-op soft tissue infection'	Yaman Ahmed (b) (4)	20 Apr 2021 22:10:35

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:59:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:56:35
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '500'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:10:35

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:59:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:57:20
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'mg (mg)'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:10:35

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:59:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:57:26
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:10:35

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:59:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:57:31
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'twice daily (BID)'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:10:35

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:59:48

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:57:29
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:10:35

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:59:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:57:32
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Oral (ORAL)'	Yaman Ahmed (b) (4)	20 Apr 2021 22:10:35

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:59:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:57:34
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:10:35

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:59:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:57:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '12 Apr 2021'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:10:35

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:59:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:57:38
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:10:35

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:59:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:58:49
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:10:35

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:00:09
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 22:10:35

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:00:12
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'No (N)'	Yaman Ahmed (b) (4)	20 Apr 2021 22:10:35

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:59:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Apr 2021 22:10:35

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 22:10:35

US3522299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:59:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 22:10:35

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 07:59:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Signature has been broken.	(b) (4), (b) (6)	01 Apr 2021 13:25:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 13:25:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:41
User entered 'No (N)'	(b) (4) Alandra White (b) (4)	24 Aug 2020 13:32:46

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:59:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:01:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:49
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered '24 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 13:25:47

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:59:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:01:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:49
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'Open Ventral Hernia repair with reduction of strangulated small bowel'	(b) (4), (b) (6)	01 Apr 2021 13:25:47

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:01:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:49
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	01 Apr 2021 13:25:47

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:59:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:01:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:49
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:25:47

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:59:48

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:02:08
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:32:09
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '24 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 15:38:16

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:59:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:02:08
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:32:09
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'CT abdomen/pelvis without IV contrast'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 15:38:16
	(b) (4)	

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:02:08
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:32:09
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 15:38:16

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:59:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:02:08
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:32:09
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4)	
	Yaman Ahmed (b) (4)	20 Apr 2021 15:38:16
	(b) (4)	

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 07:59:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:02:44
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:33:20
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '24 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:55:36

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 07:59:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:02:44
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:33:20
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '2019 nCoronavirus, PCR (covid-19) test'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:55:36

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:02:44
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:33:20
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:55:36

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 07:59:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:02:44
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:33:20
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:55:36

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 07:59:48

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:14
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:32:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '24 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:56:47

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 07:59:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:14
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:32:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'pre-op bloodwork (CBC with differential, BMP, liver profile, lipase, ABO/RH type and antibody screen, PT/INR/PTT)'	(b) (4) Yaman Ahmed (b) (4)	20 Apr 2021 21:56:47

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:14
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:32:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Adverse Event (AE)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:56:47

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 07:59:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:14
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:32:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 21:56:47

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 07:59:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:01:15
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '5 Apr 2021'	Yaman Ahmed (b) (4)	20 Apr 2021 22:08:09

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 07:59:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:01:16
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'wound/abscess/drainage culture with gram stain'	Yaman Ahmed (b) (4)	20 Apr 2021 22:08:09

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:01:18
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Diagnostic (DIAGNOSTIC)'	Yaman Ahmed (b) (4)	20 Apr 2021 22:08:09

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 07:59:48

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:01:20
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	Yaman Ahmed (b) (4)	20 Apr 2021 22:08:09

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 07:59:48

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:01:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:32:49
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '24 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 22:12:18

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 07:59:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:01:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:32:49
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'peritoneal fluid (surgical) culture and gram stain'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 22:12:18

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:01:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:32:49
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 22:12:18

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 07:59:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:01:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:32:49
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 22:12:18

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 07:59:48

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:01:50
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:31:49
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '24 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 22:13:48

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 07:59:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:01:50
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:31:49
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Surgical specimen exam (pathology)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 22:13:48

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 07:59:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:01:50
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:31:49
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 22:13:48

US3522299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 07:59:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:01:50
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:31:49
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	20 Apr 2021 22:13:48

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'USA-US131-2021-MRNA-1273-P301000014'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'Yes (Y)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'Yes (Y)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered 'Marcus'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered 'Paul'	(b) (4), (b) (6)	02 Apr 2021 14:57:00
	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered 'Zervos'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered 'Kilgore'	(b) (4), (b) (6)	02 Apr 2021 14:57:00
	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered '2799 West Grand Blvd'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered (b) (6) '	(b) (4), (b) (6)	
	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered 'Detroit'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered (b) (6) '	(b) (4), (b) (6)	
	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered empty.	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered 'MI'	(b) (4), (b) (6)	02 Apr 2021 14:57:00
	System	

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered '48202'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered (b) (6)'	(b) (4), (b) (6)	
	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'US'	(b) (4) System	02 Apr 2021 14:57:38

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 19:07:33
User entered '3'	System	03 May 2021 14:46:24
User entered '2'	System	21 Apr 2021 16:09:29
User entered '1'	System	02 Apr 2021 14:57:38

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'USA-US131-2021-MRNA-1273-P301000014'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'Yes (Y)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'Yes (Y)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

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Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered 'Marcus'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered 'Paul'	(b) (4), (b) (6)	02 Apr 2021 14:57:00
	System	

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Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered 'Zervos'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered 'Kilgore'	(b) (4), (b) (6)	02 Apr 2021 14:57:00
	System	02 Apr 2021 14:57:00

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Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered '2799 West Grand Blvd'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered (b) (6) '	(b) (4), (b) (6)	
	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered 'Detroit'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered (b) (6) '	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered empty.	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered 'MI'	(b) (4), (b) (6)	02 Apr 2021 14:57:00
	System	

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered '48202'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered (b) (6)'	(b) (4), (b) (6)	
	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'US'	(b) (4) System	02 Apr 2021 14:57:38

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 19:07:33
User entered '3'	System	03 May 2021 14:46:24
User entered '2'	System	21 Apr 2021 16:09:29
User entered '1'	System	02 Apr 2021 14:57:38

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:59:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered '02/Apr/2021 10:57'	(b) (4) System	02 Apr 2021 14:57:38

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:59:48

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)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'I'	(b) (4), (b) (6)	02 Apr 2021 14:57:38

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'USA-US131-2021-MRNA-1273-P301000014'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'Yes (Y)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'Yes (Y)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered 'Marcus'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered 'Paul'	(b) (4), (b) (6)	02 Apr 2021 14:57:00
	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered 'Zervos'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered 'Kilgore'	(b) (4), (b) (6)	02 Apr 2021 14:57:00
	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered '2799 West Grand Blvd'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered (b) (6) '	(b) (4), (b) (6)	
	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered 'Detroit'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered (b) (6) '	(b) (4), (b) (6)	
	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered empty.	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered 'MI'	(b) (4), (b) (6)	02 Apr 2021 14:57:00
	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered '48202'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered (b) (6)'	(b) (4), (b) (6)	
	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'US'	(b) (4) System	02 Apr 2021 14:57:38

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 19:07:33
User entered '3'	System	03 May 2021 14:46:24
User entered '2'	System	21 Apr 2021 16:09:29
User entered '1'	System	02 Apr 2021 14:57:38

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:59:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:19:27
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered '21/Apr/2021 09:09'	(b) (4) System	21 Apr 2021 16:09:29

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:59:48

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)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 12:19:27
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:12:14
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 16:09:29

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'USA-US131-2021-MRNA-1273-P301000014'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'Yes (Y)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'Yes (Y)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered 'Marcus'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered 'Paul'	(b) (4), (b) (6)	02 Apr 2021 14:57:00
	System	02 Apr 2021 14:57:00

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Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered 'Zervos'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered 'Kilgore'	(b) (4), (b) (6)	02 Apr 2021 14:57:00
	System	02 Apr 2021 14:57:00

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Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered '2799 West Grand Blvd'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered (b) (6) '	(b) (4), (b) (6)	
	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered 'Detroit'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered (b) (6) '	(b) (4), (b) (6)	
	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered empty.	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered 'MI'	(b) (4), (b) (6)	02 Apr 2021 14:57:00
	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered '48202'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered (b) (6)'	(b) (4), (b) (6)	
	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'US'	(b) (4) System	02 Apr 2021 14:57:38

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 19:07:33
User entered '3'	System	03 May 2021 14:46:24
User entered '2'	System	21 Apr 2021 16:09:29
User entered '1'	System	02 Apr 2021 14:57:38

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:59:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	03 May 2021 15:49:15
User entered '03/May/2021 07:46'	(b) (4) System	03 May 2021 14:46:24

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:59:48

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)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 19:07:17
User signature succeeded.	Marcus Zervos (b) (4)	03 May 2021 15:49:15
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 May 2021 14:46:24

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'USA-US131-2021-MRNA-1273-P301000014'	System	02 Apr 2021 14:57:00

US3522299

Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'Yes (Y)'	System	02 Apr 2021 14:57:00

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

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Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'Yes (Y)'	System	02 Apr 2021 14:57:00

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

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Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:26
User entered 'No (N)'	System	02 Apr 2021 14:57:00

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered 'Marcus'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered 'Paul'	(b) (4), (b) (6)	02 Apr 2021 14:57:00
	System	02 Apr 2021 14:57:00

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Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered 'Zervos'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered 'Kilgore'	(b) (4), (b) (6)	02 Apr 2021 14:57:00
	System	02 Apr 2021 14:57:00

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Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered '2799 West Grand Blvd'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered (b) (6) '	(b) (4), (b) (6)	
	System	02 Apr 2021 14:57:00

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Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:48

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered 'Detroit'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered (b) (6) '	(b) (4), (b) (6)	
	System	02 Apr 2021 14:57:00

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Form: Safety Report Form

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Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered empty.	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered 'MI'	(b) (4), (b) (6)	02 Apr 2021 14:57:00
	System	02 Apr 2021 14:57:00

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Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

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Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:09:28
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:29:58
Un-reviewed for Safety.	(b) (4)	30 Apr 2021 15:11:12
DataPoint Un-verified.	System	30 Apr 2021 15:11:12
Signature has been broken.	System	30 Apr 2021 15:11:12
User entered '48202'	System	30 Apr 2021 15:11:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
Reviewed for Safety.	(b) (4)	02 Apr 2021 14:57:26
User entered (b) (6)'	(b) (4), (b) (6)	
	System	02 Apr 2021 14:57:00

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Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:45:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:34:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:54
User entered 'US'	(b) (4) System	02 Apr 2021 14:57:38

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 19:07:33
User entered '3'	System	03 May 2021 14:46:24
User entered '2'	System	21 Apr 2021 16:09:29
User entered '1'	System	02 Apr 2021 14:57:38

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Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form (4)

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[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '03/May/2021 15:07'	System	03 May 2021 19:07:33

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Folder: SAE USA-US131-2021-MRNA-1273-P301000014

Form: Safety Report Form (4)

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Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	03 May 2021 19:07:33