US3352299 (Prod: Research Centers of America - ERG)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:13:10

All time stamps listed in this document are displayed in GMT

US3352299
Form: Participant Creation
Data signed: [(b) (4)] **28 Apr 2021 14:26:16**
Generated On: 09 Jun 2021 17:13:10

Participant ID	US3352299

mRNA-1273-P301 Completion Guidelines

US3352299

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	SCRN

US3352299

Folder: Screening

Form: Demographics

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Date of Birth (MMM yyyy)	(b) (6) 1972
Age	48
Age Units	YEARS
Age (Derived)	48
Sex	Female ○
	Male ●
Ethnicity	Hispanic or Latino ○
	Not Hispanic or Latino ●
	Not Reported ○
	Unknown ○

Race (Check All That Apply)

White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

US3352299

Folder: Screening

Form: Enrollment

Data signed: ▓▓▓ (b) (4) ▓▓▓ **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Date of Informed Consent *(dd MMM yyyy)*	1 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020

Protocol Version

- Amendment 1 ○
- Amendment 2 ○
- Amendment 3 ●
- Amendment 4 ○
- Amendment 5 ○

Was participant enrolled in the study?

- Yes ●
- No ○

If No, indicate reason for screen fail

- Withdrew Consent ○
- Inclusion/Exclusion ○
- Cohort Full ○
- Other ○

If reason for screen fail is Other, specify _____

Was this participant screened previously?

- Yes ○
- No ●

If Yes, previous participant number _____

Enrollment Trigger	1

US3352299

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Did the participant meet all eligibility criteria?   Yes ●

                                                           No ○

US3352299

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Were any significant conditions reported?　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　No ○

Condition	MYOPIA
Start date (dd MMM yyyy)	UN UNK 1986
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	
Stop Year (derived)	

US3352299

Folder: Screening

Form: Medical History (4)

Data signed: ████ (b) (4) ████ **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Condition	HYPEROPIA
Start date (dd MMM yyyy)	UN UNK 1986
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Condition	ASTIGMATISM
Start date (dd MMM yyyy)	UN UNK 1986
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	
Stop Year (derived)	

US3352299

Folder: Screening

Form: Medical History (6)

Data signed: ▨▨▨ (b) (4) ▨▨▨ **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3352299

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Condition	KIDNEY STONES
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4)   **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Condition	KIDNEY STONES
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

Folder: Screening

Form: Medical History (9)

Data signed: ████ (b) (4) ████ **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Condition	LEFT KNEE MENISCUS LESION
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

US3352299

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Condition	LEFT SHOULDER INTERNAL FIXATION DUET DISLOCATION
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ⚪
	No ⚫
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4)   **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Condition	RIGHT TIBIA FRACTURE
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

US3352299

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

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

US3352299

Folder: Screening

Form: Medical History (13)

Data signed: [(b) (4)] **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

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

Folder: Screening

Form: Medical History (14)

Data signed: ░░░░(b) (4)░░░░ **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Condition	SURGERY - BILATERAL LASIK
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ○
	No ●
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

US3352299

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Condition	SURGERY - RIGHT TIBIA FRACTURE REPAIR
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬭
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

US3352299

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Condition	SURGERY - LEFT SHOULDER DISLOCATED (FIXATION)
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

US3352299

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Condition	SURGERY - LEFT KNEE ARTHROSCOPY
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

US3352299

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 28 Apr 2021 14:28:32

Generated On: 09 Jun 2021 17:13:10

Condition	SURGERY - VASECTOMY
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

US3352299

Folder: Screening

Form: Vital Signs

Data signed: [(b) (4)] **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Were vital signs assessed?	Yes ●
	No ◯
Date of assessment *(dd MMM yyyy)*	1 SEP 2020
Time of assessment *(00:00-23:59)*	10:25 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 10:25
Height *(xxx.x)*	187.0 cm
Weight *(xxx.x)*	110.0 kg
BMI *(xxx.x)*	31.45643 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ◯
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Was the physical examination performed?	Yes ⬤
	No ◯

Date of examination *(dd MMM yyyy)*	1 SEP 2020

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

US3352299

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 14:28:32

Generated On: 09 Jun 2021 17:13:10

Occupational Risk

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

Specify _____

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False

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

US3352299

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	1 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT1

US3352299

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

What was the date of randomization? *(dd MMM yyyy)*	01 SEP 2020
What was the participant's randomization number?	110587

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	⬤

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Height	ND - Not Done
Weight	ND - Not Done

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: ░░░ **(b) (4)** ░░░ **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	1 SEP 2020
Time of assessment *(00:00-23:59)*	10:25 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 10:25
Temperature *(xxx.x)*	36.8 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	45 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ⬭
	Post-Dose ⬛
Were vital signs assessed?	Yes ⬛
	No ⬭
Date of assessment *(dd MMM yyyy)*	1 SEP 2020
Time of assessment *(00:00-23:59)*	12:14 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 12:14
Temperature *(xxx.x)*	36.5 C
Route of measurement	Oral ⬛
	Axillary ⬭
	Other ⬭
If Other, specify	
Pulse *(xxx)*	44 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	83 mmHg
Diastolic Blood Pressure units	MMHG

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.

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)*	1 SEP 2020
What was the treatment time? *(00:00-23:59)*	11:44 (24 HR)
Treatment Date and Time (derived)	1 SEP 2020 11:44
Which arm was used to give treatment?	Left Arm ●
	Right Arm ◯
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-0964527

US3352299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Was the sample collected?	Yes ⬤
	No ◯

Collection date *(dd MMM yyyy)*	1 SEP 2020
Collection time *(00:00-23:59)*	11:27 (24 HR)
Collection date and time (derived)	1 SEP 2020 11:27

US3352299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Collection date *(dd MMM yyyy)* 1 SEP 2020

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

US3352299

Folder: Visit 1 Day 1

Form: Continuing

Data signed: ▓▓▓ (b) (4) ▓▓▓ **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

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**	96.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○ No ●

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

PC Time Stamp	01 SEP 2020 12:24
PC Open Date & Time	01 SEP 2020 12:04
PC Close Date & Time	01 SEP 2020 14:34

FDA-CBER-2022-1614-0964531

US3352299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.7 °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	01 SEP 2020 21:11
PC Open Date & Time	01 SEP 2020 15:29
PC Close Date & Time	02 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:10

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.3 °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	02 SEP 2020 22:33
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	03 SEP 2020 19:26
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:10

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**	96.2 °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	05 SEP 2020 08:18
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	05 SEP 2020 22:25
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3352299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.1 °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	06 SEP 2020 22:22
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:10

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**	96.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	07 SEP 2020 22:36
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	01 SEP 2020 12:24
PC Open Date & Time	01 SEP 2020 12:04
PC Close Date & Time	01 SEP 2020 14:34

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ○
	Does not interfere with activity ●
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	01 SEP 2020 21:14
PC Open Date & Time	01 SEP 2020 15:29
PC Close Date & Time	02 SEP 2020 11:59

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ◯ Does not interfere with activity ⬤ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯ Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯ No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯ No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤ Does not interfere with activity ◯ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯ Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	02 SEP 2020 22:33
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 3

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	03 SEP 2020 19:26
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

TIMEPOINT	DAY 4
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	05 SEP 2020 08:17
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

TIMEPOINT	DAY 5

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	05 SEP 2020 22:24
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

TIMEPOINT	DAY 6

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	06 SEP 2020 22:23
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 7

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	07 SEP 2020 22:36
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

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 ◯

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●
	Yes ○

PC Time stamp	01 SEP 2020 12:25
PC Open Date & Time	01 SEP 2020 12:04
PC Close Date & Time	01 SEP 2020 14:34

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:13:10

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 ○

| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ⬤ |
| | Yes ◯ |

PC Time stamp	01 SEP 2020 21:14
PC Open Date & Time	01 SEP 2020 15:29
PC Close Date & Time	02 SEP 2020 11:59

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:13:10

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 EAB) (1725)

Yes ○

PC Time stamp	02 SEP 2020 22:33
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:10

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 ●

	Yes ◯
PC Time stamp	03 SEP 2020 19:27
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:13:10

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 ⬤

	Yes ◯
PC Time stamp	05 SEP 2020 08:17
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

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 ⬤

	Yes ◯
PC Time stamp	05 SEP 2020 22:24
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

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 ●

FDA-CBER-2022-1614-0964559

	Yes ◯
PC Time stamp	06 SEP 2020 22:24
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

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 ●

FDA-CBER-2022-1614-0964561

	Yes ◯
PC Time stamp	07 SEP 2020 22:35
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3352299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

| 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

US3352299

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4)   **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?   Yes ●

                                                                                          No ◯

Continuing Flag   1

US3352299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4)   **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

Was Contact Attempted?	Yes ⬤
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 SEP 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3352299

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?   Yes ⬤

        No ◯

Continuing Flag   1

US3352299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

| Was Contact Attempted? | Yes ⬤ |
| | No ◯ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 23 SEP 2020 |

| Please select one status for the follow-up contact | Contact Made ⬤ |
| | Contact Not Made ◯ |

Comments

If Contact Not Made, please provide Comments _____

US3352299

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?   Yes ●

                                                                                        No ○

Continuing Flag   1

US3352299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: _____ (b) (4) _____ **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT2

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4)   **28 Apr 2021 14:28:33**

Generated On: 09 Jun 2021 17:13:10

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	29 SEP 2020
Time of assessment *(00:00-23:59)*	09:10 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 09:10
Temperature *(xxx.x)*	97.6 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	56 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	83 mmHg
Diastolic Blood Pressure units	MMHG

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: [(b) (4)] **28 Apr 2021 14:28:33**

Generated On: 09 Jun 2021 17:13:10

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	29 SEP 2020
Time of assessment *(00:00-23:59)*	10:25 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 10:25
Temperature *(xxx.x)*	36.8 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	51 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

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.

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)*	29 SEP 2020
What was the treatment time? *(00:00-23:59)*	09:55 (24 HR)
Treatment Date and Time (derived)	29 SEP 2020 09:55
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

FDA-CBER-2022-1614-0964573

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	29 SEP 2020
Collection time *(00:00-23:59)*	09:29 (24 HR)
Collection date and time (derived)	29 SEP 2020 09:29

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Collection date *(dd MMM yyyy)*			29 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:24	29 SEP 2020 09:24
Nasopharyngeal Swab 2	No		

US3352299

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4)   **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?   Yes ⬤

                                           No ◯

Continuing Flag   1

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	29 SEP 2020 10:28
PC Open Date & Time	29 SEP 2020 10:15
PC Close Date & Time	29 SEP 2020 12:45

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**	96.2 °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	29 SEP 2020 19:37
PC Open Date & Time	29 SEP 2020 13:40
PC Close Date & Time	30 SEP 2020 11:59

FDA-CBER-2022-1614-0964578

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:10

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**		101.0 °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	30 SEP 2020 18:53
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	98.2 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	01 OCT 2020 20:27
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:10

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	03 OCT 2020 06:52
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.9 °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	03 OCT 2020 12:12
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3352299
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.6 °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	05 OCT 2020 07:01
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	98.2 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	05 OCT 2020 17:35
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	29 SEP 2020 10:28
PC Open Date & Time	29 SEP 2020 10:15
PC Close Date & Time	29 SEP 2020 12:45

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	29 SEP 2020 19:37
PC Open Date & Time	29 SEP 2020 13:40
PC Close Date & Time	30 SEP 2020 11:59

TIMEPOINT	DAY 2

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	30 SEP 2020 18:53
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

TIMEPOINT	DAY 3

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⭘
	Does not interfere with activity ⬤
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ⭘
	Any use of prescription pain reliever or prevents daily activity ⭘

Is there any **REDNESS AT INJECTION SITE**?	Yes ⭘
	No ⬤

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ⭘
	No ⬤

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ⭘
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ⭘
	Any use of prescription pain reliever or prevents daily activity ⭘

PC Time Stamp	01 OCT 2020 20:28
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

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	03 OCT 2020 06:52
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

TIMEPOINT	DAY 5

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	03 OCT 2020 12:13
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

TIMEPOINT	DAY 6

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	05 OCT 2020 07:02
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

TIMEPOINT	DAY 7

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	05 OCT 2020 17:36
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

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	○

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯

PC Time stamp	29 SEP 2020 10:29
PC Open Date & Time	29 SEP 2020 10:15
PC Close Date & Time	29 SEP 2020 12:45

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:13:10

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 ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯
PC Time stamp	29 SEP 2020 19:38
PC Open Date & Time	29 SEP 2020 13:40
PC Close Date & Time	30 SEP 2020 11:59

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 ⚫

	Yes ◯
PC Time stamp	30 SEP 2020 18:55
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:13:10

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 ●

	Yes ◯
PC Time stamp	01 OCT 2020 20:28
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:13:10

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 ●

Yes ◯

PC Time stamp	03 OCT 2020 06:53
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:13:10

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 ⬤

Yes ◯

PC Time stamp	03 OCT 2020 12:13
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:13:10

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 EAB) (1725)

FDA-CBER-2022-1614-0964605

	Yes ◯
PC Time stamp	05 OCT 2020 07:02
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:13:10

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 ●

	Yes ◯
PC Time stamp	05 OCT 2020 17:36
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3352299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4)   **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	6 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3352299

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: ████ (b) (4) ████ **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?   Yes ⬤

                                                                                      No ◯

Continuing Flag   1

US3352299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed:　　(b) (4)　　**28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	14 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3352299

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: [(b) (4)] **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3352299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4)   **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Was Contact Attempted?	Yes ●
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*	20 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3352299

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?　　　　　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　1

US3352299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **28 Apr 2021 14:28:33**

Generated On: 09 Jun 2021 17:13:10

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT3

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **28 Apr 2021 14:28:33**

Generated On: 09 Jun 2021 17:13:10

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	27 OCT 2020
Time of assessment *(00:00-23:59)*	09:16 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 09:16
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	48 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0964616

US3352299

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: ███ (b) (4) ███ **28 Apr 2021 14:28:33**

Generated On: 09 Jun 2021 17:13:10

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.

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **28 Apr 2021 14:28:33**

Generated On: 09 Jun 2021 17:13:10

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	27 OCT 2020
Collection time *(00:00-23:59)*	09:30 (24 HR)
Collection date and time (derived)	27 OCT 2020 09:30

US3352299

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: ███ (b) (4) ███ **28 Apr 2021 14:28:33**

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?   Yes ⬤

                                                                             No ◯

Continuing Flag   1

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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	01 NOV 2020 07:34:37
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ○
Have 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):	
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 ●
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ●
Date and time of submission	11 NOV 2020 08:34:35
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 NOV 2020 08:32:30
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 19:51:00
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚫
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚫ Yes ⚪
Have 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):	
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 ⚫
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚫
Date and time of submission	03 DEC 2020 07:27:24
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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	10 DEC 2020 19:42:34
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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	17 DEC 2020 13:18:36
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 12:11:19
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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	31 DEC 2020 07:06:53
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 06:59:09
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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	15 JAN 2021 09:44:43
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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	24 JAN 2021 18:13:15
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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	30 JAN 2021 12:00:45
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 12:01:24
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 18:56:35
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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	18 FEB 2021 08:31:47
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 FEB 2021 17:00:32
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 12:00:43
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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	12 MAR 2021 09:19:57
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 MAR 2021 09:39:39
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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	29 MAR 2021 15:34:34
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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):

Symptom	
Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0964643

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 APR 2021 07:35:07
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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	18 APR 2021 17:59:25
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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	24 APR 2021 12:17:47
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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	03 MAY 2021 12:44:11
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	06 MAY 2021 00:01
Patient Cloud Close Date & Time	10 MAY 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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°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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 MAY 2021 00:01
Patient Cloud Close Date & Time	17 MAY 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	20 MAY 2021 00:01
Patient Cloud Close Date & Time	24 MAY 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	27 MAY 2021 00:01
Patient Cloud Close Date & Time	31 MAY 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 JUN 2021 00:01
Patient Cloud Close Date & Time	07 JUN 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	**DAY 285**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ◯

FDA-CBER-2022-1614-0964661

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Date and time of submission	
Patient Cloud Open Date & Time	17 JUN 2021 00:01
Patient Cloud Close Date & Time	21 JUN 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT　　　　　　　　　　　　　　　　　　　　　　　　　　DAY 299

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Symptom	
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 ⬭

FDA-CBER-2022-1614-0964663

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 JUN 2021 00:01
Patient Cloud Close Date & Time	28 JUN 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	01 JUL 2021 00:01
Patient Cloud Close Date & Time	05 JUL 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	**DAY 313**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Symptom	
Fever (Temperature ≥ 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 ⃝

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2021 00:01
Patient Cloud Close Date & Time	12 JUL 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ○

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 327

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝
	Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝
	Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝
	Yes ⃝

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

Fever (Temperature $\geq$ 100.4°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 ⃝

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 334

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0964673

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	29 JUL 2021 00:01
Patient Cloud Close Date & Time	02 AUG 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	**DAY 341**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

Symptom	
Fever (Temperature ≥ 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 ⭕

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 AUG 2021 00:01
Patient Cloud Close Date & Time	09 AUG 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	**DAY 348**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘

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

Fever (Temperature $\geq$ 100.4°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 ⭘

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	12 AUG 2021 00:01
Patient Cloud Close Date & Time	16 AUG 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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):

Symptom	
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 ⭕

FDA-CBER-2022-1614-0964679

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 AUG 2021 00:01
Patient Cloud Close Date & Time	23 AUG 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT   **DAY 362**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ⭕

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 SEP 2021 00:01
Patient Cloud Close Date & Time	06 SEP 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	**DAY 376**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT — DAY 383

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Symptom	
Fever (Temperature ≥ 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 ⃝

FDA-CBER-2022-1614-0964687

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 SEP 2021 00:01
Patient Cloud Close Date & Time	20 SEP 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 390

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	23 SEP 2021 00:01
Patient Cloud Close Date & Time	27 SEP 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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):

Symptom	
Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0964691

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2021 00:01
Patient Cloud Close Date & Time	04 OCT 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	**DAY 404**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT DAY 411

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0964695

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT   DAY 418

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

Fever (Temperature $\geq$ 100.4°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 ⭕

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT DAY 425

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

FDA-CBER-2022-1614-0964699

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately	◯
Date and time of submission		
Patient Cloud Open Date & Time		28 OCT 2021 00:01
Patient Cloud Close Date & Time		01 NOV 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT DAY 432

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	04 NOV 2021 00:01
Patient Cloud Close Date & Time	08 NOV 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT   DAY 439

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	11 NOV 2021 00:01
Patient Cloud Close Date & Time	15 NOV 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	**DAY 446**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭

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

Fever (Temperature $\geq$ 100.4°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 ⬭

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 NOV 2021 00:01
Patient Cloud Close Date & Time	22 NOV 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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):

Symptom	
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 ◯

FDA-CBER-2022-1614-0964707

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	25 NOV 2021 00:01
Patient Cloud Close Date & Time	29 NOV 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	**DAY 460**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○
	Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ○
	Yes ○

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

Symptom	
Fever (Temperature ≥ 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 ○

FDA-CBER-2022-1614-0964709

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT　　　　　　　　　　　　　　　　　　　　DAY 467

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ≥ 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 ◯

FDA-CBER-2022-1614-0964713

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT **DAY 481**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Symptom	
Fever (Temperature ≥ 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 ⬭

FDA-CBER-2022-1614-0964715

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	23 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT **DAY 488**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭

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

Fever (Temperature $\geq$ 100.4°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 ⬭

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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):

Symptom	
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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	06 JAN 2022 00:01
Patient Cloud Close Date & Time	10 JAN 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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):

Symptom	
Fever (Temperature ≥ 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 ⭘

FDA-CBER-2022-1614-0964721

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Date and time of submission	
Patient Cloud Open Date & Time	13 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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):

Symptom	
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 ○

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	20 JAN 2022 00:01
Patient Cloud Close Date & Time	24 JAN 2022 23:59

FDA-CBER-2022-1614-0964724

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ⬭

FDA-CBER-2022-1614-0964725

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT   DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

FDA-CBER-2022-1614-0964727

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 FEB 2022 00:01
Patient Cloud Close Date & Time	07 FEB 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT DAY 530

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○
	Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ○
	Yes ○

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

Fever (Temperature ≥ 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 ○

FDA-CBER-2022-1614-0964729

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	10 FEB 2022 00:01
Patient Cloud Close Date & Time	14 FEB 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	17 FEB 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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):

Symptom	
Fever (Temperature ≥ 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 ⬭

FDA-CBER-2022-1614-0964733

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 FEB 2022 00:01
Patient Cloud Close Date & Time	28 FEB 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 MAR 2022 00:01
Patient Cloud Close Date & Time	07 MAR 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	10 MAR 2022 00:01
Patient Cloud Close Date & Time	14 MAR 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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):

Symptom	
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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	17 MAR 2022 00:01
Patient Cloud Close Date & Time	21 MAR 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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°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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 MAR 2022 00:01
Patient Cloud Close Date & Time	28 MAR 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ⬭

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	31 MAR 2022 00:01
Patient Cloud Close Date & Time	04 APR 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	07 APR 2022 00:01
Patient Cloud Close Date & Time	11 APR 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	**DAY 600**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 607

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
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 ◯

FDA-CBER-2022-1614-0964751

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 APR 2022 00:01
Patient Cloud Close Date & Time	02 MAY 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT   DAY 614

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Fever (Temperature $\geq$ 100.4°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 ⬭

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 MAY 2022 00:01
Patient Cloud Close Date & Time	09 MAY 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT DAY 621

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	12 MAY 2022 00:01
Patient Cloud Close Date & Time	16 MAY 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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):

Symptom	
Fever (Temperature ≥ 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 ⬭

FDA-CBER-2022-1614-0964757

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 MAY 2022 00:01
Patient Cloud Close Date & Time	23 MAY 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	26 MAY 2022 00:01
Patient Cloud Close Date & Time	30 MAY 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 642

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Fever (Temperature ≥ 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 ⬭

FDA-CBER-2022-1614-0964761

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 JUN 2022 00:01
Patient Cloud Close Date & Time	06 JUN 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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°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 ⦿

FDA-CBER-2022-1614-0964763

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 JUN 2022 00:01
Patient Cloud Close Date & Time	13 JUN 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2022 00:01
Patient Cloud Close Date & Time	20 JUN 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	**DAY 670**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2022 00:01
Patient Cloud Close Date & Time	11 JUL 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT   DAY 684

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 691

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭

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

Fever (Temperature ≥ 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 ⬭

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	**DAY 698**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 JUL 2022 00:01
Patient Cloud Close Date & Time	01 AUG 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ≥ 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 ○

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	04 AUG 2022 00:01
Patient Cloud Close Date & Time	08 AUG 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	11 AUG 2022 00:01
Patient Cloud Close Date & Time	15 AUG 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	**DAY 719**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0964783

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 AUG 2022 00:01
Patient Cloud Close Date & Time	22 AUG 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 726

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	01 SEP 2022 00:01
Patient Cloud Close Date & Time	05 SEP 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	**DAY 740**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT　　　　　　　　　　　　　　　　　　　　**DAY 747**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

FDA-CBER-2022-1614-0964791

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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):

Symptom	
Fever (Temperature ≥ 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 ⃝

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0964795

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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):

Symptom	
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 ⬭

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ◯

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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°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 ⬭

FDA-CBER-2022-1614-0964801

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 ≥ 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 ⭕

FDA-CBER-2022-1614-0964803

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2022 00:01
Patient Cloud Close Date & Time	31 OCT 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT	**DAY 796**

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

No ◯
Yes ◯

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

No ◯
Yes ◯

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

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

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

No ◯
Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 NOV 2022 00:01
Patient Cloud Close Date & Time	07 NOV 2022 23:59

US3352299

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:13:10

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		06 MAR 2021 12:00:54

US3352299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: [(b) (4)] **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	23 NOV 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3352299

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **28 Apr 2021 14:28:32**

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3352299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

| Was Contact Attempted? | Yes ● |
| | No ○ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*   29 DEC 2020

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments

US3352299

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: ░░░░ (b) (4) ░░░░ **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?   Yes ●

                                                                          No ◯

Continuing Flag   1

US3352299

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: **(b) (4)**   **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	27 JAN 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3352299

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4)   **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?
Yes ●
No ○

Continuing Flag   1

US3352299

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 23 FEB 2021 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments _____

US3352299

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: ⬛⬛⬛ (b) (4) ⬛⬛⬛ **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?	Yes ⬤
	No ◯

Continuing Flag	1

US3352299

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4)   **28 Apr 2021 14:28:33**

Generated On: 09 Jun 2021 17:13:10

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	22 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT4

Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **28 Apr 2021 14:28:33**
Generated On: 09 Jun 2021 17:13:10

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) _____

Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **28 Apr 2021 14:28:33**
Generated On: 09 Jun 2021 17:13:10

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.

US3352299

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **28 Apr 2021 14:28:33**

Generated On: 09 Jun 2021 17:13:10

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	22 MAR 2021
Collection time *(00:00-23:59)*	09:59 (24 HR)
Collection date and time (derived)	22 MAR 2021 09:59

US3352299

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4)   **28 Apr 2021 14:28:33**

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3352299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4)   **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	26 APR 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3352299

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: ████ (b) (4) ████ **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?   Yes ●

                                                                                     No ○

Continuing Flag   1

US3352299
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:13:10

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   _____

Is the participant continuing to the next visit?   Yes ◯

No ◯

Continuing Flag

US3352299
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:13:10

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	

Type of Contact

Clinic Visit - Scheduled ◯
Clinical Visit - Unscheduled ◯
Safety Call ◯
Convalescent Tele-visit ◯

Has the subject reported symptoms of SARS-COV-2?

Yes ◯
No ◯

Generate Next COVID-19 Assessment	Yes ◯
	No ◯

US3352299

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

Form: Visit Date

Data signed: (b) (4)   **28 Apr 2021 14:26:20**

Generated On: 09 Jun 2021 17:13:10

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	26 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	UNBLND_DECIDE

US3352299

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

Form: Unblinding

Data signed: ░░░ (b) (4) ░░░ **28 Apr 2021 14:26:20**

Generated On: 09 Jun 2021 17:13:10

Date of updated informed consent *(dd MMM yyyy)*	26 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)*	26 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	

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

Form: Immunogenicity Assessment

Data signed: **(b) (4)**   **28 Apr 2021 14:26:20**

Generated On: 09 Jun 2021 17:13:10

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	26 JAN 2021
Collection time *(00:00-23:59)*	09:43 (24 HR)
Collection date and time (derived)	26 JAN 2021 09:43

US3352299

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **28 Apr 2021 14:26:20**

Generated On: 09 Jun 2021 17:13:10

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	26 JAN 2021
Collection time *(00:00 - 23:59)*	09:35
Collection Date and Time (derived)	26 JAN 2021 09:35

US3352299

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **28 Apr 2021 14:26:17**

Generated On: 09 Jun 2021 17:13:10

Did the participant experience any adverse events?   Yes ●

                                                            No ◯

If Yes, enter details on the Adverse Events form.

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: ▨ (b) (4) ▨ **28 Apr 2021 14:26:16**

Generated On: 09 Jun 2021 17:13:10

AEID	USA-US066-2020-MRNA-1273-P30 1000005
Adverse event	DISSEMINATED VESICULAR REACTION

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)*	08 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	13 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ○
	Grade 3/Severe ○
	Grade 4 ●
Is the adverse event serious?	Yes ●
	No ○

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	11 NOV 2020
Hospital Discharge Date *(dd MMM yyyy)*	13 NOV 2020
Admitted to ICU?	Yes ○
	No ●
	Unknown ○

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 ⬤
	Related ◯
	Not Applicable ◯

Relationship to Study Procedure	
	Not Related ⬤
	Related ◯
	Not Applicable ◯

Action taken with investigational product	
	None ◯
	Dose Delayed ◯
	Investigational Product Withdrawn ◯
	Not Applicable ⬤

Other action taken (check all that apply)

None	False
Concomitant Medication	False
Concomitant Procedure	True

Outcome	
	Fatal ◯
	Not Recovered/Not Resolved ◯
	Recovered/Resolved ⬤
	Recovered/Resolved with Sequelae ◯
	Recovering/Resolving ◯
	Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

FDA-CBER-2022-1614-0964833

	SUBJECT STARTED WITH BLISTERS ALL OVER HIS BODY MORE PROMINENT TO HIS MOUTH. HE WENT TO FAMILY DOCTOR YESTERDAY AND WAS RECOMMENDED TO GO TO THE HOSPITAL IN VIEW OF HIS CLINICAL PRESENTATION. SUBJECT'S WIFE REPORTED HE WAS ADMITTED IN THE HOSPITAL YESTERDAY 11NOV2020 AT 1030 AM. HAD A SKIN BIOPSY DONE IN WHICH RESULTS ARE PENDING. SHE MENTIONED HE WAS GIVEN A STERIOD ANTIVIRAL AND PAIN MEDICATIONS. PENDING MEDICAL RECORDS.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

FDA-CBER-2022-1614-0964834

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4)   **28 Apr 2021 14:26:16**

Generated On: 09 Jun 2021 17:13:10

AEID	USA-US066-2020-MRNA-1273-P30 1000005
Adverse event	ELEVATED LIVER TRANSAMINASE LEVEL

Was this a medically-attended AE?   Yes ●   No ○

Was this a Solicited Adverse Reaction?   Yes ○   No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19?   Yes ○   No ●

Start date *(dd MMM yyyy)*	11 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?   Yes ○   No ●

If not Ongoing, end date *(dd MMM yyyy)*	13 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity   Grade 1/Mild ○   Grade 2/Moderate ○   Grade 3/Severe ●   Grade 4 ○

Is the adverse event serious?   Yes ●   No ○

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	11 NOV 2020
Hospital Discharge Date *(dd MMM yyyy)*	13 NOV 2020

Admitted to ICU?   Yes ○   No ●   Unknown ○

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: ▨ (b) (4) ▨ **28 Apr 2021 14:26:16**

Generated On: 09 Jun 2021 17:13:10

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 ⬤
	Related ◯
	Not Applicable ◯

Relationship to Study Procedure	
	Not Related ⬤
	Related ◯
	Not Applicable ◯

Action taken with investigational product	
	None ◯
	Dose Delayed ◯
	Investigational Product Withdrawn ◯
	Not Applicable ⬤

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome	
	Fatal ◯
	Not Recovered/Not Resolved ◯
	Recovered/Resolved ⬤
	Recovered/Resolved with Sequelae ◯
	Recovering/Resolving ◯
	Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative	DATA OBTAINED FROM SUBJECTS MEDICAL RECORDS WHICH HAVE BEEN REDACTED AND SUBMITTED TO SAFETY.

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

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: [(b) (4)] **28 Apr 2021 14:26:16**

Generated On: 09 Jun 2021 17:13:10

AEID	USA-US066-2020-MRNA-1273-P30 1000005
Adverse event	GENERALIZED RASH SKIN ERUPTION

Was this a medically-attended AE?   Yes ●   No ○

Was this a Solicited Adverse Reaction?   Yes ○   No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19?   Yes ○   No ●

Start date *(dd MMM yyyy)*	11 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?   Yes ○   No ●

If not Ongoing, end date *(dd MMM yyyy)*	15 DEC 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity   Grade 1/Mild ○   Grade 2/Moderate ○   Grade 3/Severe ●   Grade 4 ○

Is the adverse event serious?   Yes ●   No ○

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	11 NOV 2020
Hospital Discharge Date *(dd MMM yyyy)*	13 NOV 2020

Admitted to ICU?   Yes ○   No ●   Unknown ○

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	●
Related	○
Not Applicable	○

Relationship to Study Procedure	
Not Related	●
Related	○
Not Applicable	○

Action taken with investigational product	
None	○
Dose Delayed	○
Investigational Product Withdrawn	○
Not Applicable	●

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	
Fatal	○
Not Recovered/Not Resolved	○
Recovered/Resolved	●
Recovered/Resolved with Sequelae	○
Recovering/Resolving	○
Unknown	○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	DATA OBTAINED FROM SUBJECTS MEDICAL RECORDS WHICH HAVE BEEN REDACTED AND SUBMITTED TO SAFETY.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) **28 Apr 2021 14:26:16**

Generated On: 09 Jun 2021 17:13:10

AEID	USA-US066-2020-MRNA-1273-P30 1000009
Adverse event	BILATERAL PULMONARY EMBOLISM

Was this a medically-attended AE?   Yes ●   No ○

Was this a Solicited Adverse Reaction?   Yes ○   No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19?   Yes ○   No ●

Start date *(dd MMM yyyy)*	29 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?   Yes ○   No ●

If not Ongoing, end date *(dd MMM yyyy)*	1 DEC 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity   Grade 1/Mild ○   Grade 2/Moderate ○   Grade 3/Severe ○   Grade 4 ●

Is the adverse event serious?   Yes ●   No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	29 NOV 2020
Hospital Discharge Date *(dd MMM yyyy)*	1 DEC 2020

Admitted to ICU?   Yes ○   No ●   Unknown ○

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) **28 Apr 2021 14:26:16**

Generated On: 09 Jun 2021 17:13:10

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	⬤
	Related	◯
	Not Applicable	◯

Relationship to Study Procedure	Not Related	⬤
	Related	◯
	Not Applicable	◯

Action taken with investigational product	None	◯
	Dose Delayed	◯
	Investigational Product Withdrawn	◯
	Not Applicable	⬤

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	Fatal	◯
	Not Recovered/Not Resolved	◯
	Recovered/Resolved	⬤
	Recovered/Resolved with Sequelae	◯
	Recovering/Resolving	◯
	Unknown	◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT HAVE A HISTORY OF PULMONARY EMBOLISM, THIS INCIDENT OCCURED AFTER HE CAME BACK FROM A TRIP, HE IS NOW TAKEN XARELTO 15 MG. SUBJECT IS CURRENTLY DOING WELL.

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) **28 Apr 2021 14:26:16**

Generated On: 09 Jun 2021 17:13:10

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

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) **28 Apr 2021 14:26:16**

Generated On: 09 Jun 2021 17:13:10

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

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related ●
	Related ○
	Not Applicable ○

Relationship to Study Procedure	Not Related ●
	Related ○
	Not Applicable ○

Action taken with investigational product	None ●
	Dose Delayed ○
	Investigational Product Withdrawn ○
	Not Applicable ○

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	Fatal ○
	Not Recovered/Not Resolved ○
	Recovered/Resolved ●
	Recovered/Resolved with Sequelae ○
	Recovering/Resolving ○
	Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	

Narrative	SUBJECT HAD A BILATERAL PULMONARY EMBOLISM NOVEMBER 29, 2020. PNEUMONIA WAS PART OF THE REPORTABLE CONDITIONS UPON MEDICAL RECORDS REVIEWED.

Serious Adverse Event Derived (CSA Programming Field Ony)	0

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) **28 Apr 2021 14:26:16**

Generated On: 09 Jun 2021 17:13:10

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

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **28 Apr 2021 14:26:20**

Generated On: 09 Jun 2021 17:13:10

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

                                                                                                                                        No ○

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: [(b) (4)] **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	SYNTHROID

Prophylaxis

Yes ◯
No ⬤

Indication	HYPOTHYROIDISM
Dose per administration	200

Dose unit

mg ◯
ug ⬤
mL ◯
g ◯
IU ◯
tablet ◯
capsule ◯
puff ◯
Other ◯

If dose unit is Other, specify

Frequency

once daily ⬤
twice daily ◯
three times daily ◯
four times daily ◯
every other day ◯
every week ◯
every month ◯
as needed ◯
once ◯
unknown ◯
other ◯

If frequency is Other, specify

Route of administration

Oral ⬤
Topical ◯
Subcutaneous ◯
Transdermal ◯
Intraocular ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

	Intramuscular ⬭
	Respiratory (Inhalation) ⬭
	Intralesional ⬭
	Intraperiteoneal ⬭
	Nasal ⬭
	Vaginal ⬭
	Rectal ⬭
	Intravenous ⬭
	Intravenous Bolus ⬭
	Intravenous Drip ⬭
	Other ⬭
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2005
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ⬭
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ⬭
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ⬭
	803 ⬭
	804 ⬤

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	BETHAMETHASONE 0.05%
Prophylaxis	Yes ○
	No ●
Indication	GENERALIZED RASK SKIN ERUPTION
Dose per administration	1
Dose unit	mg ○
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ●
If dose unit is Other, specify	APPLICATION
Frequency	once daily ○
	twice daily ●
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ○
	Topical ●
	Subcutaneous ○
	Transdermal ○

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify

Start date *(dd MMM yyyy)*	13 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤

If not Ongoing, End date *(dd MMM yyyy)*	15 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤

Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	PREDNISONE

Prophylaxis	Yes ○
	No ●

Indication	GENERALIZED RASH SKIN ERUPTION

Dose per administration	40

Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○

If dose unit is Other, specify _____

Frequency	once daily ●
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○

If frequency is Other, specify _____

Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○

Intraocular ◯

Intramuscular ◯

Respiratory (Inhalation) ◯

Intralesional ◯

Intraperiteoneal ◯

Nasal ◯

Vaginal ◯

Rectal ◯

Intravenous ◯

Intravenous Bolus ◯

Intravenous Drip ◯

Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	13 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	15 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: [(b) (4)] **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	VALTREX

Prophylaxis	Yes	⚪
	No	⬤

Indication	GENRALIZED RASH SKIN ERUPTION

Dose per administration	1

Dose unit	mg	⚪
	ug	⚪
	mL	⚪
	g	⬤
	IU	⚪
	tablet	⚪
	capsule	⚪
	puff	⚪
	Other	⚪

If dose unit is Other, specify	

Frequency	once daily	⚪
	twice daily	⚪
	three times daily	⬤
	four times daily	⚪
	every other day	⚪
	every week	⚪
	every month	⚪
	as needed	⚪
	once	⚪
	unknown	⚪
	other	⚪

If frequency is Other, specify	

Route of administration	Oral	⬤
	Topical	⚪
	Subcutaneous	⚪
	Transdermal	⚪

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	15 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

FDA-CBER-2022-1614-0964853

Name of Medication	CLARITIN (LORATADINE)

Prophylaxis

Yes ◯

No ⬤

Indication

GENERALIZED RASK SKIN ERUPTION

Dose per administration

10

Dose unit

mg ⬤

ug ◯

mL ◯

g ◯

IU ◯

tablet ◯

capsule ◯

puff ◯

Other ◯

If dose unit is Other, specify

Frequency

once daily ⬤

twice daily ◯

three times daily ◯

four times daily ◯

every other day ◯

every week ◯

every month ◯

as needed ◯

once ◯

unknown ◯

other ◯

If frequency is Other, specify

Route of administration

Oral ⬤

Topical ◯

Subcutaneous ◯

Transdermal ◯

FDA-CBER-2022-1614-0964854

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

	Intraocular ◯
	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	13 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4)   **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	DILAUDID

Prophylaxis
- Yes ◯
- No ⬤

Indication	GENERALIZED RASH SKIN ERUPTION
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 ◯

PRODUCTION RELEASE (v12.003 EAB) (1725)

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	⬤

If route of administration is Other, specify	INTRAVENOUS PUSH
Start date *(dd MMM yyyy)*	11 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	13 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

FDA-CBER-2022-1614-0964857

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: ▨▨▨ (b) (4) ▨▨▨ **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	ALUMINUM HYDROXIDE/ DIPHENHYDRAMINE/ LIDOCAINE/ MAGNESIUM HYDROXIDE/ SIMETHICORE TOPICAL
Prophylaxis	Yes ◯
	No ⬤
Indication	GENERALIZED RASH SKIN ERUPTION
Dose per administration	40/5
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	EVERY THREE HOURS
Route of administration	Oral ◯

Topical	⬤
Subcutaneous	◯
Transdermal	◯
Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	13 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	PEPCID
Prophylaxis	Yes ●
	No ○
Indication	GASTRIC PROPHYLAXIS
Dose per administration	20 / 2
Dose unit	mg ○
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ●
If dose unit is Other, specify	MG / ML
Frequency	once daily ○
	twice daily ●
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ○
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ⬤
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	13 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: ░░░░ **(b) (4)** ░░░░ **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	PREDNISONE

Prophylaxis

Yes ⚪
No ⚫

Indication	GENERALIZED RASH SKIN ERUPTION.

Dose per administration	10

Dose unit

mg ⚫
ug ⚪
mL ⚪
g ⚪
IU ⚪
tablet ⚪
capsule ⚪
puff ⚪
Other ⚪

If dose unit is Other, specify

Frequency

once daily ⚫
twice daily ⚪
three times daily ⚪
four times daily ⚪
every other day ⚪
every week ⚪
every month ⚪
as needed ⚪
once ⚪
unknown ⚪
other ⚪

If frequency is Other, specify

Route of administration

Oral ⚫
Topical ⚪
Subcutaneous ⚪
Transdermal ⚪

	Intraocular ◯
	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	21 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	HYDROMORPHONE

Prophylaxis	Yes ⚪
	No ⚫

Indication	GENERALIZED RASH SKIN ERUPTION

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 ⚪

PRODUCTION RELEASE (v12.003 EAB) (1725)

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	11 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	ONDANSETRON

Prophylaxis

Yes ◯
No ⬤

Indication	GENERALIZED RASH SKIN ERUPTION
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 ◯
	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ⬤
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	11 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: ░░░ (b) (4) ░░░ **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	PREDNISONE

Prophylaxis

Yes ○
No ⬤

Indication	GENERALIZED RASH SKIN ERUPTION
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 ○

PRODUCTION RELEASE (v12.003 EAB) (1725)

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	18 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

FDA-CBER-2022-1614-0964869

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: [(b) (4)] **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	PREDNISONE

Prophylaxis

Yes ◯
No ●

Indication	GENERALIZED RASH SKIN ERUPTION
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 ◯

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	20 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	PREDNISONE

Prophylaxis	Yes ⚪
	No ⚫

Indication	GENERALIZED RASH SKIN ERUPTION

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 ⚪

FDA-CBER-2022-1614-0964872

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	12 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: [redacted] **(b) (4)** **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	SODIUM CHLORIDE 0.9%
Prophylaxis	Yes ⚪
	No ⚫
Indication	GENERALIZED RASH SKIN ERUPTION
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 ⚪

PRODUCTION RELEASE (v12.003 EAB) (1725)

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	12 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	TRIAMCINOLONE 0.01%
Prophylaxis	Yes ◯
	No ⬤
Indication	GENERALIZED RASH SKIN ERUPTION
Dose per administration	1
Dose unit	mg ◯
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ⬤
If dose unit is Other, specify	APPLICATION
Frequency	once daily ◯
	twice daily ◯
	three times daily ⬤
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ◯
	Topical ⬤
	Subcutaneous ◯
	Transdermal ◯

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	13 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

FDA-CBER-2022-1614-0964877

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	ACETAMINOPHEN

Prophylaxis	Yes ○
	No ●

Indication	GENERALIZED RASH SKIN ERUPTION

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 ○

PRODUCTION RELEASE (v12.003 EAB) (1725)

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	11 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	XARELTO

Prophylaxis	Yes ○
	No ●

Indication	PULMONAY EMBOLISM

Dose per administration	15

Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○

If dose unit is Other, specify _____

Frequency	once daily ○
	twice daily ●
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○

If frequency is Other, specify _____

Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	29 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	15 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	CEFTRIAXONE

Prophylaxis	
Yes	◯
No	●

Indication	PNEUMONIA
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	◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ⬤
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	29 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	29 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: [(b) (4)] **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	PREMIX DEXTROSE 5 %

Prophylaxis

- Yes ○
- No ●

Indication	BILATERAL PULMONARY EMBOLISM
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 ○

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3352299

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Data signed: (b) (4) **28 Apr 2021 14:26:18**
Generated On: 09 Jun 2021 17:13:10

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	30 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	30 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	PREMIX DEXTROSE 5 %

Prophylaxis	Yes ⚪
	No ⚫

Indication	BILATERAL PULMONARY EMBOLISM

Dose per administration	26

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	26 ML EVERY HOUR

Route of administration	Oral ⚪
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify

Start date *(dd MMM yyyy)*	30 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤

If not Ongoing, End date *(dd MMM yyyy)*   1 DEC 2020

Was this medication taken for solicited event?	Yes ◯
	No ⬤

Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	HEPARIN

Prophylaxis
- Yes ○
- No ●

Indication	BILATERAL PULMONARY EMBOLISM
Dose per administration	5000

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 ○

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	30 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	30 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: **(b) (4)**   **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	HEPARIN

Prophylaxis   Yes ◯

    No ⬤

Indication	BILATERAL PULMONARY EMBOLISM
Dose per administration	26

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   26 ML PER HOUR

Route of administration   Oral ◯

Topical ◯

Subcutaneous ◯

Transdermal ◯

	Intraocular ◯
	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ⬤
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	30 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	1 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: **(b) (4)**   **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	XARELTO
Prophylaxis	Yes ⬭
	No ⬤
Indication	PULMONARY EMBOLISM
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 ⬭
	Intraocular ⬭

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: [(b) (4)] **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	IOPAMIDOL

Prophylaxis
Yes ○
No ●

Indication	BILATERAL PULMONARY EMBOLISM
Dose per administration	50

Dose unit
mg ○
ug ○
mL ●
g ○
IU ○
tablet ○
capsule ○
puff ○
Other ○

If dose unit is Other, specify _____

Frequency
once daily ○
twice daily ○
three times daily ○
four times daily ○
every other day ○
every week ○
every month ○
as needed ○
once ●
unknown ○
other ○

If frequency is Other, specify _____

Route of administration
Oral ○
Topical ○
Subcutaneous ○
Transdermal ○

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	29 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	29 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: [REDACTED] **(b) (4)** **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	AZITHROMYCIN

Prophylaxis
- Yes ○
- No ●

Indication	PNEUMONIA
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 ○
- Intraocular ○

	Intramuscular ⚪
	Respiratory (Inhalation) ⚪
	Intralesional ⚪
	Intraperiteoneal ⚪
	Nasal ⚪
	Vaginal ⚪
	Rectal ⚪
	Intravenous ⚫
	Intravenous Bolus ⚪
	Intravenous Drip ⚪
	Other ⚪

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	29 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ⚪
	No ⚫
If not Ongoing, End date *(dd MMM yyyy)*	29 NOV 2020
Was this medication taken for solicited event?	Yes ⚪
	No ⚫
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ⚪
	803 ⚪
	804 ⚪

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: [(b) (4)] **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	MEDROL DOSE PAK

Prophylaxis

Yes ○
No ●

Indication	BILATERAL PULMONARY EMBOLISM
Dose per administration	24

Dose unit

mg ●
ug ○
mL ○
g ○
IU ○
tablet ○
capsule ○
puff ○
Other ○

If dose unit is Other, specify _____

Frequency

once daily ○
twice daily ○
three times daily ○
four times daily ○
every other day ○
every week ○
every month ○
as needed ○
once ●
unknown ○
other ○

If frequency is Other, specify _____

Route of administration

Oral ●
Topical ○
Subcutaneous ○
Transdermal ○

PRODUCTION RELEASE (v12.003
EAB) (1725)

	Intraocular ⬭
	Intramuscular ⬭
	Respiratory (Inhalation) ⬭
	Intralesional ⬭
	Intraperiteoneal ⬭
	Nasal ⬭
	Vaginal ⬭
	Rectal ⬭
	Intravenous ⬭
	Intravenous Bolus ⬭
	Intravenous Drip ⬭
	Other ⬭

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ⬭
	No ⬛
If not Ongoing, End date *(dd MMM yyyy)*	01 DEC 2020
Was this medication taken for solicited event?	Yes ⬭
	No ⬛
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ⬭
	803 ⬭
	804 ⬭

FDA-CBER-2022-1614-0964899

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: [(b) (4)] **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	MEDROL DOSE PAK

Prophylaxis

Yes ◯

No ⬤

Indication	BILATERAL PULMONARY EMBOLISM
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 ◯

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	02 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	02 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	MEDROL DOSE PAK

Prophylaxis

Yes ◯

No ⬤

Indication — BILATERAL PULMONARY EMBOLISM

Dose per administration — 16

Dose unit

mg ⬤
ug ◯
mL ◯
g ◯
IU ◯
tablet ◯
capsule ◯
puff ◯
Other ◯

If dose unit is Other, specify _____

Frequency

once daily ◯
twice daily ◯
three times daily ◯
four times daily ◯
every other day ◯
every week ◯
every month ◯
as needed ◯
once ⬤
unknown ◯
other ◯

If frequency is Other, specify _____

Route of administration

Oral ⬤
Topical ◯
Subcutaneous ◯
Transdermal ◯

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	03 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	03 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	MEDROL DOSE PAK

Prophylaxis

Yes ◯

No ⬤

Indication	BILATERAL PULMONARY EMBOLISM
Dose per administration	12

Dose unit

mg ⬤

ug ◯

mL ◯

g ◯

IU ◯

tablet ◯

capsule ◯

puff ◯

Other ◯

If dose unit is Other, specify _____

Frequency

once daily ◯

twice daily ◯

three times daily ◯

four times daily ◯

every other day ◯

every week ◯

every month ◯

as needed ◯

once ⬤

unknown ◯

other ◯

If frequency is Other, specify _____

Route of administration

Oral ⬤

Topical ◯

Subcutaneous ◯

Transdermal ◯

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	04 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	04 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: ░░░░ **(b) (4)** ░░░░ **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	MEDROL DOSE PAK
Prophylaxis	Yes ⚪
	No ⬤
Indication	BILATERAL PULMONARY EMBOLISM
Dose per administration	8
Dose unit	mg ⬤
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚪
If dose unit is Other, specify	
Frequency	once daily ⚪
	twice daily ⚪
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚪
	once ⬤
	unknown ⚪
	other ⚪
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	05 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	05 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	MEDROL DOSE PAK

Prophylaxis

Yes ⚪
No ⬤

Indication	BILATERAL PULMONARY EMBOLISM
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	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify

Start date *(dd MMM yyyy)*	06 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	06 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	OMEPRAZOLE

Prophylaxis

Yes ●

No ○

Indication	GASTROESOPHAGEAL REFLUX DISEASE,

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 ○

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	03 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

FDA-CBER-2022-1614-0964911

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: [(b) (4)] **28 Apr 2021 14:26:18**

Generated On: 09 Jun 2021 17:13:10

Name of Medication	MORPHINE
Prophylaxis	Yes ⭕
	No ⚫
Indication	PULMONARY EMBOLISM
Dose per administration	2
Dose unit	mg ⭕
	ug ⭕
	mL ⭕
	g ⭕
	IU ⭕
	tablet ⭕
	capsule ⭕
	puff ⭕
	Other ⚫
If dose unit is Other, specify	2 MG/ 1 ML
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	EVERY FOUR HOURS
Route of administration	Oral ⭕
	Topical ⭕
	Subcutaneous ⭕
	Transdermal ⭕
	Intraocular ⭕

PRODUCTION RELEASE (v12.003
EAB) (1725)

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ⬤
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify

Start date *(dd MMM yyyy)*	29 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤

If not Ongoing, End date *(dd MMM yyyy)*	30 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤

Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **28 Apr 2021 14:26:20**

Generated On: 09 Jun 2021 17:13:10

Were any concomitant procedures performed?   Yes ●

No ◯

If yes, please complete Concomitant Procedures form.

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: [(b) (4)] **28 Apr 2021 14:26:20**

Generated On: 09 Jun 2021 17:13:10

Procedure/Surgery date (*dd MMM yyyy*)	Procedure/Surgery	Indication	If indication is Other, specify
11 NOV 2020	PUNCH BIOPSY	Adverse Event	
13 NOV 2020	SKIN BIOPSY RIGHT ARM	Adverse Event	
12 NOV 2020	SKIN BIOPSY	Adverse Event	
29 NOV 2020	CHEST CT WITH CONTRAST	Adverse Event	
29 NOV 2020	CHEST X RAY 2 VIEWS	Adverse Event	
30 NOV 2020	ECHO DOPPLER	Adverse Event	
30 NOV 2020	EKG	Adverse Event	
01 DEC 2020	VENOUS DOPPLER BILATERAL LOWER EXTREMETIES	Adverse Event	

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 ◯

SAEID	USA-US066-2020-MRNA-1273-P30 1000005
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

FDA-CBER-2022-1614-0964917

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: ░░░░ (b) (4) ░░░░ **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

SAEID	USA-US066-2020-MRNA-1273-P30 1000005
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	13/NOV/2020 08:23
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

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

SAEID	USA-US066-2020-MRNA-1273-P30 1000005
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	18/NOV/2020 14:33
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

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4)   **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

SAEID	USA-US066-2020-MRNA-1273-P30 1000005
Serious	Yes ⬤ No ◯
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ⬤ No ◯
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	25/NOV/2020 17:24
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

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

SAEID	USA-US066-2020-MRNA-1273-P30 1000005
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	09/DEC/2020 19:06
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

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

SAEID	USA-US066-2020-MRNA-1273-P30 1000005
Serious	Yes ●
	No ○
Death	Yes ○
	No ●
Life threatening	Yes ○
	No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ●
	No ○
Persistent or significant disability or incapacity	Yes ○
	No ●
Congenital anomaly or birth defect	Yes ○
	No ●
Other medically important event	Yes ○
	No ●
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	11/DEC/2020 14:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: **(b) (4)**   **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

SAEID	USA-US066-2020-MRNA-1273-P30 1000005
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	19/FEB/2021 10:30
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

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Data signed: (b) (4) **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

SAEID	USA-US066-2020-MRNA-1273-P30 1000005
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	08/MAR/2021 09:45
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

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Data signed: [(b) (4)] **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

SAEID	USA-US066-2020-MRNA-1273-P30 1000005
Serious	Yes ●
	No ○
Death	Yes ○
	No ●
Life threatening	Yes ○
	No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ●
	No ○
Persistent or significant disability or incapacity	Yes ○
	No ●
Congenital anomaly or birth defect	Yes ○
	No ●
Other medically important event	Yes ○
	No ●
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	22/MAR/2021 13:10
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

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (9)

Data signed: (b) (4) **28 Apr 2021 14:26:21**

Generated On: 09 Jun 2021 17:13:10

SAEID	USA-US066-2020-MRNA-1273-P30 1000005
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	02/APR/2021 05:58
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

SAEID	USA-US066-2020-MRNA-1273-P30 1000009
Serious	Yes ⬤ No ◯
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ⬤ No ◯
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) **28 Apr 2021 14:26:20**

Generated On: 09 Jun 2021 17:13:10

SAEID	USA-US066-2020-MRNA-1273-P30 1000009
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	09/DEC/2020 17:52
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

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) **28 Apr 2021 14:26:20**

Generated On: 09 Jun 2021 17:13:10

SAEID	USA-US066-2020-MRNA-1273-P30 1000009
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	10/DEC/2020 02:06
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

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: ░░░ (b) (4) ░░░ **28 Apr 2021 14:26:20**

Generated On: 09 Jun 2021 17:13:10

SAEID	USA-US066-2020-MRNA-1273-P30 1000009
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/FEB/2021 14:15
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

US3352299 (Prod: Research Centers of America - ERG)

US3352299

Form: Participant Creation

Generated On: 09 Jun 2021 17:13:10

Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:16:46
User entered 'US3352299'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:14:48

US3352299

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:13:10

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:41:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:46:06

US3352299
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:13:10

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:41:42
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:14:50

US3352299

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:41:42
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Sep 2020 17:46:06

US3352299
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:13:10
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'SCRN'	System	01 Sep 2020 17:46:06

US3352299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:10

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:42:00
User entered (b) (6) 1972'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:14:51

US3352299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:10

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:42:00
User entered '48'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:10

Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'YEARS'	System	01 Sep 2020 17:46:28

US3352299
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:13:10

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '48'	System	01 Sep 2020 16:22:56

US3352299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:10

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:42:00
User entered 'Male (M)'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:10

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:42:00
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:10

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:42:00
User entered '1'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

PRODUCTION RELEASE (v12.003
EAB) (1725)

449 of 2877

US3352299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:10

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:42:00
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:10

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:42:00
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:10

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:42:00
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:10

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:42:00
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:10

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:42:00
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:13:10
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:42:00
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:13:10
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:42:00
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:10

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:42:00
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:13:10

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:59:25
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 16:22:56

US3352299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:10

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Sep 2020'	System	01 Sep 2020 16:22:56

US3352299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:10

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '2020'	System	01 Sep 2020 16:22:56

US3352299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:10

Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:59:25
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	01 Sep 2020 16:22:56

US3352299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:10

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:59:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 16:22:56

US3352299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:10

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:59:25
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 16:22:56

US3352299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:10

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:59:25
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 16:22:56

US3352299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:10

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:59:25
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 16:22:56

US3352299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:10

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:59:25
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:14:50

US3352299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:10

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '1'	System	01 Sep 2020 16:23:02

US3352299

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:13:10

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:00:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 16:23:02

US3352299

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:13:10

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:00:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:46:49

US3352299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:48:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:48:50
Data point term sent to Coder	System	01 Sep 2020 17:48:01
User entered 'MYOPIA'	(b) (4), (b) (6)	01 Sep 2020 17:47:15

US3352299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 1986'	(b) (4), (b) (6)	01 Sep 2020 17:47:15

US3352299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:47:15

US3352299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:10

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
Query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 14) was reported (UN UNK 1998-UN UNK 1998). Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:10:02
User opened query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 14) was reported (UN UNK 1998-UN UNK 1998). Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:06:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:47:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:47:15

FDA-CBER-2022-1614-0964968

Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:13:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:47:15

US3352299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 1986'	System	01 Sep 2020 17:47:15

US3352299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '1986'	System	01 Sep 2020 17:47:15

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered empty.	System	01 Sep 2020 17:47:15

US3352299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:10

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered empty.	System	01 Sep 2020 17:47:15

US3352299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Hyperopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:48:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:48:51
Data point term sent to Coder	System	01 Sep 2020 17:48:02
User entered 'HYPEROPIA'	(b) (4), (b) (6)	01 Sep 2020 17:47:39

US3352299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 1986'	(b) (4), (b) (6)	01 Sep 2020 17:47:39

US3352299
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:13:10
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:47:39

US3352299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:10

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
Query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 14) was reported (UN UNK 1998-UN UNK 1998). Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:11:03
User opened query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 14) was reported (UN UNK 1998-UN UNK 1998). Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:07:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:47:39

FDA-CBER-2022-1614-0964977

US3352299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:47:39

US3352299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:47:39

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 1986'	System	01 Sep 2020 17:47:39

US3352299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '1986'	System	01 Sep 2020 17:47:39

US3352299
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:13:10
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered empty.	System	01 Sep 2020 17:47:39

US3352299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:10

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered empty.	System	01 Sep 2020 17:47:39

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Astigmatism, LLT: Astigmatism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:49:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:49:54
Data point term sent to Coder	System	01 Sep 2020 17:49:03
User entered 'ASTIGMATISM'	(b) (4), (b) (6)	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:30:25
DataPoint Un-verified.	Matthew Muniz (b) (4)	09 Dec 2020 19:15:17
User entered 'un UNK 1986' reason for change: Data Entry Error	Matthew Muniz (b) (4)	09 Dec 2020 19:15:17
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:30:02
User closed query 'Please clarify in source, there is no data in source stating that this is unknown, please update source. ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 15:32:21
Query 'Please clarify in source, there is no data in source stating that this is unknown, please update source. ' answered with 'updated' (Site from CRA).	Matthew Muniz (b) (4)	09 Dec 2020 19:15:30
DataPoint Un-verified.	Matthew Muniz (b) (4)	09 Dec 2020 19:15:17
User entered '0' reason for change: Data Entry Error	Matthew Muniz (b) (4)	09 Dec 2020 19:15:17
User opened query 'Please clarify in source, there is no data in source stating that this is unknown, please update source. ' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 21:08:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '1'	(b) (4), (b) (6)	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:10

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
Query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 14) was reported (UN UNK 1998-UN UNK 1998). Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:11:37
User opened query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 14) was reported (UN UNK 1998-UN UNK 1998). Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:07:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 1986'	System	09 Dec 2020 19:15:17
User entered empty.	System	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '1986'	System	09 Dec 2020 19:15:17
User entered empty.	System	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:10

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered empty.	System	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:10

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered empty.	System	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
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)	01 Sep 2020 17:49:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:49:54
Data point term sent to Coder	System	01 Sep 2020 17:49:03
User entered 'HYPOTHYROIDISM'	(b) (4), (b) (6)	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 2005'	(b) (4), (b) (6)	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:10

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 2005'	System	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '2005'	System	01 Sep 2020 17:48:33

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered empty.	System	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:10

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered empty.	System	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiases, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:49:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:49:53
Data point term sent to Coder	System	01 Sep 2020 17:49:04
User entered 'KIDNEY STONES'	(b) (4), (b) (6)	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 2012'	(b) (4), (b) (6)	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:10

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 2012'	(b) (4), (b) (6)	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:48:51

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 2012'	System	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '2012'	System	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:10

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 2012'	System	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:10

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '2012'	System	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiases, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:50:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:50:45
Data point term sent to Coder	System	01 Sep 2020 17:50:07
User entered 'KIDNEY STONES'	(b) (4), (b) (6)	01 Sep 2020 17:49:08

FDA-CBER-2022-1614-0965014

US3352299

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 2019'	(b) (4), (b) (6)	01 Sep 2020 17:49:08

US3352299

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:49:08

US3352299
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:13:10
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:49:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 2019'	(b) (4), (b) (6)	01 Sep 2020 17:49:08

US3352299

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:49:08

US3352299

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 2019'	System	01 Sep 2020 17:49:08

US3352299

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '2019'	System	01 Sep 2020 17:49:08

US3352299

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:10

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 2019'	System	01 Sep 2020 17:49:08

US3352299

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:10

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '2019'	System	01 Sep 2020 17:49:08

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus lesion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 21:34:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 21:34:38
Data point term sent to Coder	System	01 Sep 2020 17:51:07
User entered 'LEFT KNEE MENISCUS LESION'	(b) (4), (b) (6)	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 2008'	(b) (4), (b) (6)	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:10

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 2008'	(b) (4), (b) (6)	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 2008'	System	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '2008'	System	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:10

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 2008'	System	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:10

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '2008'	System	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Shoulder operation, LLT: Shoulder operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 07:24:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 07:24:41
Data point term sent to Coder	System	01 Sep 2020 17:53:11
User entered 'LEFT SHOULDER INTERNAL FIXATION DUET DISLOCATION'	(b) (4), (b) (6)	01 Sep 2020 17:52:18

US3352299

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:52:18

US3352299

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:52:18

US3352299
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:13:10
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:52:18

US3352299

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:52:18

US3352299

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:52:18

US3352299

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 1998'	System	01 Sep 2020 17:52:18

US3352299

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '1998'	System	01 Sep 2020 17:52:18

US3352299

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:10

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 1998'	System	01 Sep 2020 17:52:18

US3352299
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:13:10
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '1998'	System	01 Sep 2020 17:52:18

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Tibia fracture, LLT: Tibia fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:54:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:54:46
Data point term sent to Coder	System	01 Sep 2020 17:54:12
User entered 'RIGHT TIBIA FRACTURE'	(b) (4), (b) (6)	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:10

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 1998'	System	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '1998'	System	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:10

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 1998'	System	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:10

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '1998'	System	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Bradycardia, LLT: Bradycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:54:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:54:46
Data point term sent to Coder	System	01 Sep 2020 17:54:12
User entered 'BRADYCARDIA'	(b) (4), (b) (6)	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 2000'	(b) (4), (b) (6)	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:10

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 2000'	System	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '2000'	System	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:10

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered empty.	System	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:10

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered empty.	System	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:13:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:58:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:58:49
Data point term sent to Coder	System	01 Sep 2020 17:58:21
User entered 'PULMONARY EMBOLISM'	(b) (4), (b) (6)	01 Sep 2020 17:57:41

US3352299

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:13:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 2018'	(b) (4), (b) (6)	01 Sep 2020 17:57:41

US3352299

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:57:41

US3352299

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:13:10

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:57:41

US3352299

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 2018'	(b) (4), (b) (6)	01 Sep 2020 17:57:41

US3352299

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:13:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:57:41

US3352299

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:13:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 2018'	System	01 Sep 2020 17:57:41

US3352299

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:13:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '2018'	System	01 Sep 2020 17:57:41

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 2018'	System	01 Sep 2020 17:57:41

US3352299
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 17:13:10

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '2018'	System	01 Sep 2020 17:57:41

US3352299
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 17:13:10
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:05:41
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:08:17
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Keratomileusis, LLT: LASIK eye surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:11:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:11:47
Data point term sent to Coder	System	01 Sep 2020 17:58:21
User entered 'SURGERY - BILATERAL LASIK'	(b) (4), (b) (6)	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:10

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 1998'	System	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '1998'	System	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:10

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 1998'	System	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:10

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '1998'	System	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Fracture treatments (excl skull and spine), PT: Fracture treatment, LLT: Fracture repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 12:15:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 12:15:15
Data point term sent to Coder	System	01 Sep 2020 17:59:22
User entered 'SURGERY - RIGHT TIBIA FRACTURE REPAIR'	(b) (4), (b) (6)	01 Sep 2020 17:58:49

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:10

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 1998'	System	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '1998'	System	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:10

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 1998'	System	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:10

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '1998'	System	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
Query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition LEFT SHOULDER INTERNAL FIXATION DUET DISLOCATION (MH# 10). If yes, please ensure only one entry is recorded. ' canceled (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 20:23:08
User opened query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition LEFT SHOULDER INTERNAL FIXATION DUET DISLOCATION (MH# 10). If yes, please ensure only one entry is recorded. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:08:45
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Shoulder operation, LLT: Shoulder operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 09:00:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 09:00:23
Data point term sent to Coder	System	01 Sep 2020 18:00:25
User entered 'SURGERY - LEFT SHOULDER DISLOCATED (FIXATION)'	(b) (4), (b) (6)	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:10

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:59:55

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 1998'	System	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '1998'	System	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:10

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 1998'	System	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:10

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '1998'	System	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User coded data point as SOC: Investigations, HLGT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Arthroscopy L knee - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:13:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:13:09
Data point term sent to Coder	System	01 Sep 2020 18:00:26
User entered 'SURGERY - LEFT KNEE ARTHROSCOPY'	(b) (4), (b) (6)	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 2008'	(b) (4), (b) (6)	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:10

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 2008'	(b) (4), (b) (6)	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 2008'	System	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '2008'	System	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:10

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 2008'	System	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:10

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '2008'	System	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:02:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:02:52
Data point term sent to Coder	System	01 Sep 2020 18:01:26
User entered 'SURGERY - VASECTOMY'	(b) (4), (b) (6)	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 2014'	(b) (4), (b) (6)	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:10

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered 'UN UNK 2014'	(b) (4), (b) (6)	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:01:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 2014'	System	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '2014'	System	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:10

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'Jan 2014'	System	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:10

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '2014'	System	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:25:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:25:49
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:01:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:25:49
User entered '10:25'	(b) (4), (b) (6)	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '1 Sep 2020 10:25'	System	01 Sep 2020 18:01:58

Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:25:49
User entered '187.0' cm	(b) (4), (b) (6)	01 Sep 2020 18:01:58
DataPoint set to visible.	System	01 Sep 2020 16:23:02

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:25:49
User entered '110.0' kg	(b) (4), (b) (6)	01 Sep 2020 18:01:58
DataPoint set to visible.	System	01 Sep 2020 16:23:02

US3352299
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered '31.45643'	System	01 Sep 2020 18:01:58
DataPoint set to visible.	System	01 Sep 2020 16:23:02

US3352299
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'kg/m2'	System	01 Sep 2020 18:01:58
DataPoint set to visible.	System	01 Sep 2020 16:23:02

US3352299
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:25:49
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:25:49
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:01:58

US3352299
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:25:49
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:01:58

US3352299
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:25:49
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:01:58

US3352299
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'bpm'	System	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:25:49
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'breaths/min'	System	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:25:49
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:01:58

US3352299
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'mmHg'	System	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:25:49
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:01:58

Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User entered 'mmHg'	System	01 Sep 2020 18:01:58

US3352299
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38

US3352299

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:10

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:26:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:02:06

US3352299

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:10

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:26:21
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:02:06

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:26
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:26
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:10

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)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:26
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:10

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)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:26
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:26
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:10

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)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:26
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:10

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)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:26
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:10

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)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:26
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:10

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)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:26
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:10

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)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:26
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:10

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)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:26
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:13:10
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:45
DataPoint Un-verified.		05 Mar 2021 16:24:36
User entered 'No (N)' reason for change: Data Entry Error		05 Mar 2021 16:24:36
DataPoint Verified.		02 Dec 2020 21:30:26
User entered 'Yes (Y)'		01 Sep 2020 18:02:52

US3352299
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:13:10
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:44
User closed query 'Shopping and eating at restaurants is not an occupation, please remove from EDC and source, you may select no risk identified. ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 15:32:42
User closed query 'Occupational Risk is recorded as OTHER, but specification was not provided. Please provide.' (Site from System).	System	05 Mar 2021 16:24:36
Query 'Shopping and eating at restaurants is not an occupation, please remove from EDC and source, you may select no risk identified. ' answered with 'DATA UPDATED ' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:24:21
User opened query 'Occupational Risk is recorded as OTHER, but specification was not provided. Please provide.' (Site from System).	System	05 Mar 2021 16:24:04
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 16:24:04
User entered empty; reason for change Data Entry Error		05 Mar 2021 16:24:04
DataPoint Verified.		02 Dec 2020 21:30:26
User opened query 'Shopping and eating at restaurants is not an occupation, please remove from EDC and source, you may select no risk identified. ' (Site from CRA).		02 Dec 2020 21:30:14
User entered 'GOES TO SHOP AND RESTAURANT'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:10

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:10

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:26
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:10

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)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:26
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:10

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)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:26
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:10

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)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:26
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:26
User entered '1'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:10

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:10

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:26
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:13:10

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:33:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:03:10

US3352299

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:13:10

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:33:06
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:03:10

US3352299
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:33:06
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Sep 2020 18:03:10

US3352299
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:13:10
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User entered 'VISIT1'	System	01 Sep 2020 18:03:10

US3352299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
User closed query 'Please place IRT Confirmation for Screening and randomization in source. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 15:55:00
Query 'Please place IRT Confirmation for Screening and randomization in source. ' answered with 'IRT confirmation for screening and randomization has been placed in source' (Site from CRA).	(b) (4), (b) (6)	14 Dec 2020 20:00:13
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:35:21
User opened query 'Please place IRT Confirmation for Screening and randomization in source. ' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 21:35:16
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:34:32

US3352299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:10

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:35:21
User entered '110587'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:34:32

US3352299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:10

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:35:21
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:34:32

US3352299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:10

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)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:35:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:03:30

US3352299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:10

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)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:35:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:03:30

US3352299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:35:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:03:30

US3352299
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:13:10
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:35:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:03:30

US3352299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:10

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:35:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:03:30

US3352299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:10

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:35:21
User entered 'No (N)'	Wanda Delgado (b) (4)	02 Nov 2020 17:59:26
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:54:03
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:54:02

US3352299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:13:10
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:10

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:10

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:10

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered '10:25'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User entered '1 Sep 2020 10:25'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered '36.8' C	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered '45'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:13:10
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User entered 'bpm'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered '15'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User entered 'breaths/min'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered '134'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User entered 'mmHg'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered '81'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User entered 'mmHg'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:10

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:10

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
Query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' canceled (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 21:48:40
User opened query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 21:51:45
User entered '12:14'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User entered '1 Sep 2020 12:14'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered '36.5' C	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:05:02

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 09:08:37
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'VITAL SIGNS REPEATED AND RECORDED UNDER UNSCHEDULED VITAL SIGNS' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:17:28
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Sep 2020 18:05:02
User entered '44'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User entered 'bpm'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered '14'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User entered 'breaths/min'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered '131'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User entered 'mmHg'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:23
User entered '83'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User entered 'mmHg'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:10

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:42
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:05:42

FDA-CBER-2022-1614-0965219

US3352299

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:10

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:42
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:05:42

US3352299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:10

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:38:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 16:23:24

US3352299
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:13:10
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:38:05
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 16:23:24

US3352299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:10

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)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:38:05
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 16:23:24

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 16:23:24

FDA-CBER-2022-1614-0965224

US3352299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:10

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:38:05
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 16:23:24

US3352299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:10

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:38:05
User entered '11:44'	(b) (4), (b) (6)	01 Sep 2020 16:23:24

US3352299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:10

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User entered '1 Sep 2020 11:44'	System	01 Sep 2020 16:23:24

US3352299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:10

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:38:05
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	01 Sep 2020 16:23:24

US3352299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:10

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:38:05
User entered 'ONCE'	System	01 Sep 2020 16:23:24

US3352299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 16:23:24

US3352299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:10

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:38:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:06:10

US3352299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:10

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:38:35
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:06:10

US3352299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:38:35
User entered '11:27'	(b) (4), (b) (6)	01 Sep 2020 18:06:10

US3352299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:10

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User entered '1 Sep 2020 11:27'	System	01 Sep 2020 18:06:10

US3352299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:13:10

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:38:46
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:06:22

US3352299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:10

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	01 Sep 2020 18:06:22

US3352299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:10

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:38:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:06:22

US3352299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:38:46
User entered '11:11'	(b) (4), (b) (6)	01 Sep 2020 18:06:22

US3352299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:10

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User entered '1 Sep 2020 11:11'	System	01 Sep 2020 18:06:22

US3352299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:10

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	01 Sep 2020 18:06:22

US3352299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:10

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:38:46
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:06:22

US3352299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:38:46
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:06:22

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User entered empty.	System	01 Sep 2020 18:06:22

US3352299
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:38:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:06:27

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:50
User entered '1'	System	01 Sep 2020 18:06:27

US3352299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:13:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:23:52', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '75da0372-0a2d-4ae1-8bf8-220d7adc1688'	System	01 Sep 2020 16:24:15
User entered 'Yes (Y)'	System	01 Sep 2020 16:24:15

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:24:02', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '75da0372-0a2d-4ae1-8bf8-220d7adc1688'	System	01 Sep 2020 16:24:15
User entered '96.1'	System	01 Sep 2020 16:24:15

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:24:06', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '75da0372-0a2d-4ae1-8bf8-220d7adc1688'	System	01 Sep 2020 16:24:15
User entered 'No (N)'	System	01 Sep 2020 16:24:15

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:24:11', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '75da0372-0a2d-4ae1-8bf8-220d7adc1688'	System	01 Sep 2020 16:24:15
User entered '01 Sep 2020 12:24'	System	01 Sep 2020 16:24:15

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '01 Sep 2020 12:04'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '01 Sep 2020 14:34'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:11:45', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '0a73e54b-76e3-4b69-af6f-75f7f261ce81'	System	02 Sep 2020 01:12:01
User entered 'Yes (Y)'	System	02 Sep 2020 01:12:01

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:11:50', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '0a73e54b-76e3-4b69-af6f-75f7f261ce81'	System	02 Sep 2020 01:12:01
User entered '97.7'	System	02 Sep 2020 01:12:01

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:11:54', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '0a73e54b-76e3-4b69-af6f-75f7f261ce81'	System	02 Sep 2020 01:12:01
User entered 'No (N)'	System	02 Sep 2020 01:12:01

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:11:59', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '0a73e54b-76e3-4b69-af6f-75f7f261ce81'	System	02 Sep 2020 01:12:01
User entered '01 Sep 2020 21:11'	System	02 Sep 2020 01:12:01

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '01 Sep 2020 15:29'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 2'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:32:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'b0b834c7-4466-47c6-b9b1-1ad3b7154807'	System	03 Sep 2020 02:33:29
User entered 'Yes (Y)'	System	03 Sep 2020 02:33:29

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:18', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'b0b834c7-4466-47c6-b9b1-1ad3b7154807'	System	03 Sep 2020 02:33:29
User entered '96.3'	System	03 Sep 2020 02:33:29

US3352299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:22', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'b0b834c7-4466-47c6-b9b1-1ad3b7154807'	System	03 Sep 2020 02:33:29
User entered 'No (N)'	System	03 Sep 2020 02:33:29

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:10

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:26', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'b0b834c7-4466-47c6-b9b1-1ad3b7154807'	System	03 Sep 2020 02:33:29
User entered '02 Sep 2020 22:33'	System	03 Sep 2020 02:33:29

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 3'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:10', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a57ba51b-ad1e-4fab-bad3-1592ea4bd560'	System	03 Sep 2020 23:26:24
User entered 'Yes (Y)'	System	03 Sep 2020 23:26:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:15', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a57ba51b-ad1e-4fab-bad3-1592ea4bd560'	System	03 Sep 2020 23:26:24
User entered '97.2'	System	03 Sep 2020 23:26:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:20', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a57ba51b-ad1e-4fab-bad3-1592ea4bd560'	System	03 Sep 2020 23:26:24
User entered 'No (N)'	System	03 Sep 2020 23:26:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:10

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:23', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a57ba51b-ad1e-4fab-bad3-1592ea4bd560'	System	03 Sep 2020 23:26:24
User entered '03 Sep 2020 19:26'	System	03 Sep 2020 23:26:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 4'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:13:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:50', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '2c851465-185a-4681-8bd2-18a4e8f9a2c0'	System	05 Sep 2020 12:18:41
User entered 'Yes (Y)'	System	05 Sep 2020 12:18:41

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:18:31', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '2c851465-185a-4681-8bd2-18a4e8f9a2c0'	System	05 Sep 2020 12:18:41
User entered '96.2'	System	05 Sep 2020 12:18:41

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:10

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:18:34', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '2c851465-185a-4681-8bd2-18a4e8f9a2c0'	System	05 Sep 2020 12:18:41
User entered 'No (N)'	System	05 Sep 2020 12:18:41

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:10

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:18:37', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '2c851465-185a-4681-8bd2-18a4e8f9a2c0'	System	05 Sep 2020 12:18:41
User entered '05 Sep 2020 08:18'	System	05 Sep 2020 12:18:41

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 5'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:25:04', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '284738ff-c0a3-4b9a-8743-75daa0d84a3e'	System	06 Sep 2020 02:25:17
User entered 'Yes (Y)'	System	06 Sep 2020 02:25:17

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:25:08', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '284738ff-c0a3-4b9a-8743-75daa0d84a3e'	System	06 Sep 2020 02:25:17
User entered '97.5'	System	06 Sep 2020 02:25:17

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:25:11', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '284738ff-c0a3-4b9a-8743-75daa0d84a3e'	System	06 Sep 2020 02:25:17
User entered 'No (N)'	System	06 Sep 2020 02:25:17

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:10

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:25:14', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '284738ff-c0a3-4b9a-8743-75daa0d84a3e'	System	06 Sep 2020 02:25:17
User entered '05 Sep 2020 22:25'	System	06 Sep 2020 02:25:17

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 6'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:13:10
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:22:43', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f48ffdb3-42e5-4f6d-87f5-a7ab51b4b24a'	System	07 Sep 2020 02:22:56
User entered 'Yes (Y)'	System	07 Sep 2020 02:22:56

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:22:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f48ffdb3-42e5-4f6d-87f5-a7ab51b4b24a'	System	07 Sep 2020 02:22:56
User entered '97.1'	System	07 Sep 2020 02:22:56

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:22:51', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f48ffdb3-42e5-4f6d-87f5-a7ab51b4b24a'	System	07 Sep 2020 02:22:56
User entered 'No (N)'	System	07 Sep 2020 02:22:56

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:10

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:22:53', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f48ffdb3-42e5-4f6d-87f5-a7ab51b4b24a'	System	07 Sep 2020 02:22:56
User entered '06 Sep 2020 22:22'	System	07 Sep 2020 02:22:56

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 7'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:36:23', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7b93c992-7bbe-49d1-a1b2-a277a52cdee2'	System	08 Sep 2020 02:36:40
User entered 'Yes (Y)'	System	08 Sep 2020 02:36:40

US3352299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:13:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:36:27', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7b93c992-7bbe-49d1-a1b2-a277a52cdee2'	System	08 Sep 2020 02:36:40
User entered '96.8'	System	08 Sep 2020 02:36:40

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:36:31', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7b93c992-7bbe-49d1-a1b2-a277a52cdee2'	System	08 Sep 2020 02:36:40
User entered 'No (N)'	System	08 Sep 2020 02:36:40

US3352299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:13:10
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:36:34', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7b93c992-7bbe-49d1-a1b2-a277a52cdee2'	System	08 Sep 2020 02:36:40
User entered '07 Sep 2020 22:36'	System	08 Sep 2020 02:36:40

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:24:23', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1f2e9368-bb18-4892-931f-b299566a570b'	System	01 Sep 2020 16:24:53
User entered 'None (1)'	System	01 Sep 2020 16:24:53

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:24:30', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1f2e9368-bb18-4892-931f-b299566a570b'	System	01 Sep 2020 16:24:53
User entered 'No (N)'	System	01 Sep 2020 16:24:53

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:24:40', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1f2e9368-bb18-4892-931f-b299566a570b'	System	01 Sep 2020 16:24:53
User entered 'No (N)'	System	01 Sep 2020 16:24:53

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:24:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1f2e9368-bb18-4892-931f-b299566a570b'	System	01 Sep 2020 16:24:53
User entered 'None (1)'	System	01 Sep 2020 16:24:53

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:24:50', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1f2e9368-bb18-4892-931f-b299566a570b'	System	01 Sep 2020 16:24:53
User entered '01 Sep 2020 12:24'	System	01 Sep 2020 16:24:53

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '01 Sep 2020 12:04'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '01 Sep 2020 14:34'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:12:30', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'c144d588-5d53-4ec9-a2ed-77dd7d490af4'	System	02 Sep 2020 01:14:27
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 01:14:27

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:12:55', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'c144d588-5d53-4ec9-a2ed-77dd7d490af4'	System	02 Sep 2020 01:14:27
User entered 'No (N)'	System	02 Sep 2020 01:14:27

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:11', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'c144d588-5d53-4ec9-a2ed-77dd7d490af4'	System	02 Sep 2020 01:14:27
User entered 'No (N)'	System	02 Sep 2020 01:14:27

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:20', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'c144d588-5d53-4ec9-a2ed-77dd7d490af4'	System	02 Sep 2020 01:14:27
User entered 'None (1)'	System	02 Sep 2020 01:14:27

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:26', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'c144d588-5d53-4ec9-a2ed-77dd7d490af4'	System	02 Sep 2020 01:14:27
User entered '01 Sep 2020 21:14'	System	02 Sep 2020 01:14:27

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:13:10
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '01 Sep 2020 15:29'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 2'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:31', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '26282362-6f12-436c-bf74-e84254fa40a5'	System	03 Sep 2020 02:33:43
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 02:33:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:34', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '26282362-6f12-436c-bf74-e84254fa40a5'	System	03 Sep 2020 02:33:43
User entered 'No (N)'	System	03 Sep 2020 02:33:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:36', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '26282362-6f12-436c-bf74-e84254fa40a5'	System	03 Sep 2020 02:33:43
User entered 'No (N)'	System	03 Sep 2020 02:33:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:39', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '26282362-6f12-436c-bf74-e84254fa40a5'	System	03 Sep 2020 02:33:43
User entered 'None (1)'	System	03 Sep 2020 02:33:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:10

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:42', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '26282362-6f12-436c-bf74-e84254fa40a5'	System	03 Sep 2020 02:33:43
User entered '02 Sep 2020 22:33'	System	03 Sep 2020 02:33:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 3'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:29', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a22842f5-6a6f-4598-9015-8301e1d29fcb'	System	03 Sep 2020 23:26:43
User entered 'None (1)'	System	03 Sep 2020 23:26:43

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:13:10
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:32', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a22842f5-6a6f-4598-9015-8301e1d29fcb'	System	03 Sep 2020 23:26:43
User entered 'No (N)'	System	03 Sep 2020 23:26:43

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:13:10
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:34', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a22842f5-6a6f-4598-9015-8301e1d29fcb'	System	03 Sep 2020 23:26:43
User entered 'No (N)'	System	03 Sep 2020 23:26:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:38', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a22842f5-6a6f-4598-9015-8301e1d29fcb'	System	03 Sep 2020 23:26:43
User entered 'None (1)'	System	03 Sep 2020 23:26:43

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:13:10
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:41', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a22842f5-6a6f-4598-9015-8301e1d29fcb'	System	03 Sep 2020 23:26:43
User entered '03 Sep 2020 19:26'	System	03 Sep 2020 23:26:43

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:13:10
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 4'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:27', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'aa965510-db9a-41c2-bc50-6a6235009af5'	System	05 Sep 2020 12:17:43
User entered 'None (1)'	System	05 Sep 2020 12:17:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:32', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'aa965510-db9a-41c2-bc50-6a6235009af5'	System	05 Sep 2020 12:17:43
User entered 'No (N)'	System	05 Sep 2020 12:17:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:34', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'aa965510-db9a-41c2-bc50-6a6235009af5'	System	05 Sep 2020 12:17:43
User entered 'No (N)'	System	05 Sep 2020 12:17:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:38', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'aa965510-db9a-41c2-bc50-6a6235009af5'	System	05 Sep 2020 12:17:43
User entered 'None (1)'	System	05 Sep 2020 12:17:43

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:13:10
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:42', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'aa965510-db9a-41c2-bc50-6a6235009af5'	System	05 Sep 2020 12:17:43
User entered '05 Sep 2020 08:17'	System	05 Sep 2020 12:17:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 5'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:36', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd3710611-bd3f-47d4-92e3-c0e2e71b2a6e'	System	06 Sep 2020 02:25:02
User entered 'None (1)'	System	06 Sep 2020 02:25:02

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:39', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd3710611-bd3f-47d4-92e3-c0e2e71b2a6e'	System	06 Sep 2020 02:25:02
User entered 'No (N)'	System	06 Sep 2020 02:25:02

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:52', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd3710611-bd3f-47d4-92e3-c0e2e71b2a6e'	System	06 Sep 2020 02:25:02
User entered 'No (N)'	System	06 Sep 2020 02:25:02

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:55', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd3710611-bd3f-47d4-92e3-c0e2e71b2a6e'	System	06 Sep 2020 02:25:02
User entered 'None (1)'	System	06 Sep 2020 02:25:02

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:13:10
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:58', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd3710611-bd3f-47d4-92e3-c0e2e71b2a6e'	System	06 Sep 2020 02:25:02
User entered '05 Sep 2020 22:24'	System	06 Sep 2020 02:25:02

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 6'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:22:57', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1b8bd912-1b47-4a0c-a79e-de1c7f52185d'	System	07 Sep 2020 02:23:07
User entered 'None (1)'	System	07 Sep 2020 02:23:07

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:22:59', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1b8bd912-1b47-4a0c-a79e-de1c7f52185d'	System	07 Sep 2020 02:23:07
User entered 'No (N)'	System	07 Sep 2020 02:23:07

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:23:01', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1b8bd912-1b47-4a0c-a79e-de1c7f52185d'	System	07 Sep 2020 02:23:07
User entered 'No (N)'	System	07 Sep 2020 02:23:07

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:23:03', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1b8bd912-1b47-4a0c-a79e-de1c7f52185d'	System	07 Sep 2020 02:23:07
User entered 'None (1)'	System	07 Sep 2020 02:23:07

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:13:10
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:23:05', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1b8bd912-1b47-4a0c-a79e-de1c7f52185d'	System	07 Sep 2020 02:23:07
User entered '06 Sep 2020 22:23'	System	07 Sep 2020 02:23:07

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 7'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:35:59', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c0f8ddc-319b-41ca-ba11-9bb6969c4311'	System	08 Sep 2020 02:36:40
User entered 'None (1)'	System	08 Sep 2020 02:36:40

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:36:02', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c0f8ddc-319b-41ca-ba11-9bb6969c4311'	System	08 Sep 2020 02:36:40
User entered 'No (N)'	System	08 Sep 2020 02:36:40

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:36:05', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c0f8ddc-319b-41ca-ba11-9bb6969c4311'	System	08 Sep 2020 02:36:40
User entered 'No (N)'	System	08 Sep 2020 02:36:40

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:36:08', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c0f8ddc-319b-41ca-ba11-9bb6969c4311'	System	08 Sep 2020 02:36:40
User entered 'None (1)'	System	08 Sep 2020 02:36:40

US3352299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:13:10
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:36:12', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c0f8ddc-319b-41ca-ba11-9bb6969c4311'	System	08 Sep 2020 02:36:40
User entered '07 Sep 2020 22:36'	System	08 Sep 2020 02:36:40

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:24:59', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1381893e-ac8a-4e74-82c3-ae9d9fa5d413'	System	01 Sep 2020 16:25:39
User entered 'None (0)'	System	01 Sep 2020 16:25:39

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:25:10', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1381893e-ac8a-4e74-82c3-ae9d9fa5d413'	System	01 Sep 2020 16:25:39
User entered 'None (0)'	System	01 Sep 2020 16:25:39

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:13:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:25:14', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1381893e-ac8a-4e74-82c3-ae9d9fa5d413'	System	01 Sep 2020 16:25:39
User entered 'None (0)'	System	01 Sep 2020 16:25:39

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:25:17', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1381893e-ac8a-4e74-82c3-ae9d9fa5d413'	System	01 Sep 2020 16:25:39
User entered 'None (0)'	System	01 Sep 2020 16:25:39

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:25:19', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1381893e-ac8a-4e74-82c3-ae9d9fa5d413'	System	01 Sep 2020 16:25:39
User entered 'None (0)'	System	01 Sep 2020 16:25:39

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:25:22', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1381893e-ac8a-4e74-82c3-ae9d9fa5d413'	System	01 Sep 2020 16:25:39
User entered 'None (0)'	System	01 Sep 2020 16:25:39

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:25:33', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1381893e-ac8a-4e74-82c3-ae9d9fa5d413'	System	01 Sep 2020 16:25:39
User entered 'No (N)'	System	01 Sep 2020 16:25:39

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:25:36', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1381893e-ac8a-4e74-82c3-ae9d9fa5d413'	System	01 Sep 2020 16:25:39
User entered '01 Sep 2020 12:25'	System	01 Sep 2020 16:25:39

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '01 Sep 2020 12:04'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '01 Sep 2020 14:34'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:30', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4513ad0f-018c-4169-ae22-1b174cfaf9ec'	System	02 Sep 2020 01:14:53
User entered 'None (0)'	System	02 Sep 2020 01:14:53

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:13:10
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:32', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4513ad0f-018c-4169-ae22-1b174cfaf9ec'	System	02 Sep 2020 01:14:53
User entered 'None (0)'	System	02 Sep 2020 01:14:53

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:36', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4513ad0f-018c-4169-ae22-1b174cfaf9ec'	System	02 Sep 2020 01:14:53
User entered 'None (0)'	System	02 Sep 2020 01:14:53

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:38', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4513ad0f-018c-4169-ae22-1b174cfaf9ec'	System	02 Sep 2020 01:14:53
User entered 'None (0)'	System	02 Sep 2020 01:14:53

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:13:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:40', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4513ad0f-018c-4169-ae22-1b174cfaf9ec'	System	02 Sep 2020 01:14:53
User entered 'None (0)'	System	02 Sep 2020 01:14:53

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:13:10
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:42', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4513ad0f-018c-4169-ae22-1b174cfaf9ec'	System	02 Sep 2020 01:14:53
User entered 'None (0)'	System	02 Sep 2020 01:14:53

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:49', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4513ad0f-018c-4169-ae22-1b174cfaf9ec'	System	02 Sep 2020 01:14:53
User entered 'No (N)'	System	02 Sep 2020 01:14:53

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:51', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4513ad0f-018c-4169-ae22-1b174cfaf9ec'	System	02 Sep 2020 01:14:53
User entered '01 Sep 2020 21:14'	System	02 Sep 2020 01:14:53

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '01 Sep 2020 15:29'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 2'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:13:10
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:45', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '00298c96-48e8-486a-bc6f-3e1c3939e95a'	System	03 Sep 2020 02:33:59
User entered 'None (0)'	System	03 Sep 2020 02:33:59

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:13:10
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '00298c96-48e8-486a-bc6f-3e1c3939e95a'	System	03 Sep 2020 02:33:59
User entered 'None (0)'	System	03 Sep 2020 02:33:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:49', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '00298c96-48e8-486a-bc6f-3e1c3939e95a'	System	03 Sep 2020 02:33:59
User entered 'None (0)'	System	03 Sep 2020 02:33:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:50', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '00298c96-48e8-486a-bc6f-3e1c3939e95a'	System	03 Sep 2020 02:33:59
User entered 'None (0)'	System	03 Sep 2020 02:33:59

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:13:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:52', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '00298c96-48e8-486a-bc6f-3e1c3939e95a'	System	03 Sep 2020 02:33:59
User entered 'None (0)'	System	03 Sep 2020 02:33:59

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:13:10
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:54', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '00298c96-48e8-486a-bc6f-3e1c3939e95a'	System	03 Sep 2020 02:33:59
User entered 'None (0)'	System	03 Sep 2020 02:33:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:56', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '00298c96-48e8-486a-bc6f-3e1c3939e95a'	System	03 Sep 2020 02:33:59
User entered 'No (N)'	System	03 Sep 2020 02:33:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:10

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:58', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '00298c96-48e8-486a-bc6f-3e1c3939e95a'	System	03 Sep 2020 02:33:59
User entered '02 Sep 2020 22:33'	System	03 Sep 2020 02:33:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 3'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:13:10
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:45', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a71affcf-a7af-4587-a157-3e1166d78349'	System	03 Sep 2020 23:27:09
User entered 'None (0)'	System	03 Sep 2020 23:27:09

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:13:10
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a71affcf-a7af-4587-a157-3e1166d78349'	System	03 Sep 2020 23:27:09
User entered 'None (0)'	System	03 Sep 2020 23:27:09

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:13:10
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:51', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a71affcf-a7af-4587-a157-3e1166d78349'	System	03 Sep 2020 23:27:09
User entered 'None (0)'	System	03 Sep 2020 23:27:09

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:13:10
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:55', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a71affcf-a7af-4587-a157-3e1166d78349'	System	03 Sep 2020 23:27:09
User entered 'None (0)'	System	03 Sep 2020 23:27:09

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:13:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:58', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a71affcf-a7af-4587-a157-3e1166d78349'	System	03 Sep 2020 23:27:09
User entered 'None (0)'	System	03 Sep 2020 23:27:09

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:27:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a71affcf-a7af-4587-a157-3e1166d78349'	System	03 Sep 2020 23:27:09
User entered 'None (0)'	System	03 Sep 2020 23:27:09

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:27:04', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a71affcf-a7af-4587-a157-3e1166d78349'	System	03 Sep 2020 23:27:09
User entered 'No (N)'	System	03 Sep 2020 23:27:09

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:10

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:27:06', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a71affcf-a7af-4587-a157-3e1166d78349'	System	03 Sep 2020 23:27:09
User entered '03 Sep 2020 19:27'	System	03 Sep 2020 23:27:09

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

FDA-CBER-2022-1614-0965409

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 4'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:13:10
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:05', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '90ae032e-de0d-4d39-be77-2544633affd5'	System	05 Sep 2020 12:17:24
User entered 'None (0)'	System	05 Sep 2020 12:17:24

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:13:10
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:07', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '90ae032e-de0d-4d39-be77-2544633affd5'	System	05 Sep 2020 12:17:24
User entered 'None (0)'	System	05 Sep 2020 12:17:24

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:13:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:09', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '90ae032e-de0d-4d39-be77-2544633affd5'	System	05 Sep 2020 12:17:24
User entered 'None (0)'	System	05 Sep 2020 12:17:24

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:13:10
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:14', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '90ae032e-de0d-4d39-be77-2544633affd5'	System	05 Sep 2020 12:17:24
User entered 'None (0)'	System	05 Sep 2020 12:17:24

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:13:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:16', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '90ae032e-de0d-4d39-be77-2544633affd5'	System	05 Sep 2020 12:17:24
User entered 'None (0)'	System	05 Sep 2020 12:17:24

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:13:10
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:18', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '90ae032e-de0d-4d39-be77-2544633affd5'	System	05 Sep 2020 12:17:24
User entered 'None (0)'	System	05 Sep 2020 12:17:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:20', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '90ae032e-de0d-4d39-be77-2544633affd5'	System	05 Sep 2020 12:17:24
User entered 'No (N)'	System	05 Sep 2020 12:17:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:10

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:23', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '90ae032e-de0d-4d39-be77-2544633affd5'	System	05 Sep 2020 12:17:24
User entered '05 Sep 2020 08:17'	System	05 Sep 2020 12:17:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 5'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:13:10
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:11', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c239e64-733f-4337-aec8-73a05031f580'	System	06 Sep 2020 02:24:36
User entered 'None (0)'	System	06 Sep 2020 02:24:36

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:13:10
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:13', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c239e64-733f-4337-aec8-73a05031f580'	System	06 Sep 2020 02:24:36
User entered 'None (0)'	System	06 Sep 2020 02:24:36

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:13:10
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:15', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c239e64-733f-4337-aec8-73a05031f580'	System	06 Sep 2020 02:24:36
User entered 'None (0)'	System	06 Sep 2020 02:24:36

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:13:10
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:16', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c239e64-733f-4337-aec8-73a05031f580'	System	06 Sep 2020 02:24:36
User entered 'None (0)'	System	06 Sep 2020 02:24:36

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:13:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:18', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c239e64-733f-4337-aec8-73a05031f580'	System	06 Sep 2020 02:24:36
User entered 'None (0)'	System	06 Sep 2020 02:24:36

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:13:10
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:24', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c239e64-733f-4337-aec8-73a05031f580'	System	06 Sep 2020 02:24:36
User entered 'None (0)'	System	06 Sep 2020 02:24:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:29', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c239e64-733f-4337-aec8-73a05031f580'	System	06 Sep 2020 02:24:36
User entered 'No (N)'	System	06 Sep 2020 02:24:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:10

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:31', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c239e64-733f-4337-aec8-73a05031f580'	System	06 Sep 2020 02:24:36
User entered '05 Sep 2020 22:24'	System	06 Sep 2020 02:24:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 6'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:13:10
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:23:16', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd23e5829-7cec-4544-bfa7-3456ce1add98'	System	07 Sep 2020 02:24:07
User entered 'None (0)'	System	07 Sep 2020 02:24:07

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:13:10
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:23:18', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd23e5829-7cec-4544-bfa7-3456ce1add98'	System	07 Sep 2020 02:24:07
User entered 'None (0)'	System	07 Sep 2020 02:24:07

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:13:10
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:23:20', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd23e5829-7cec-4544-bfa7-3456ce1add98'	System	07 Sep 2020 02:24:07
User entered 'None (0)'	System	07 Sep 2020 02:24:07

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:23:40', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd23e5829-7cec-4544-bfa7-3456ce1add98'	System	07 Sep 2020 02:24:07
User entered 'None (0)'	System	07 Sep 2020 02:24:07

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:23:42', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd23e5829-7cec-4544-bfa7-3456ce1add98'	System	07 Sep 2020 02:24:07
User entered 'None (0)'	System	07 Sep 2020 02:24:07

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:13:10
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:23:45', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd23e5829-7cec-4544-bfa7-3456ce1add98'	System	07 Sep 2020 02:24:07
User entered 'None (0)'	System	07 Sep 2020 02:24:07

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:24:01', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd23e5829-7cec-4544-bfa7-3456ce1add98'	System	07 Sep 2020 02:24:07
User entered 'No (N)'	System	07 Sep 2020 02:24:07

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:10

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:24:04', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd23e5829-7cec-4544-bfa7-3456ce1add98'	System	07 Sep 2020 02:24:07
User entered '06 Sep 2020 22:24'	System	07 Sep 2020 02:24:07

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 7'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:35:33', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1a0faf01-c85c-4a67-9122-d8f0260f4876'	System	08 Sep 2020 02:36:36
User entered 'None (0)'	System	08 Sep 2020 02:36:36

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:13:10
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:35:35', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1a0faf01-c85c-4a67-9122-d8f0260f4876'	System	08 Sep 2020 02:36:36
User entered 'None (0)'	System	08 Sep 2020 02:36:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:35:38', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1a0faf01-c85c-4a67-9122-d8f0260f4876'	System	08 Sep 2020 02:36:36
User entered 'None (0)'	System	08 Sep 2020 02:36:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:35:42', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1a0faf01-c85c-4a67-9122-d8f0260f4876'	System	08 Sep 2020 02:36:36
User entered 'None (0)'	System	08 Sep 2020 02:36:36

US3352299
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:13:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:35:45', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1a0faf01-c85c-4a67-9122-d8f0260f4876'	System	08 Sep 2020 02:36:36
User entered 'None (0)'	System	08 Sep 2020 02:36:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:35:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1a0faf01-c85c-4a67-9122-d8f0260f4876'	System	08 Sep 2020 02:36:36
User entered 'None (0)'	System	08 Sep 2020 02:36:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:35:52', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1a0faf01-c85c-4a67-9122-d8f0260f4876'	System	08 Sep 2020 02:36:36
User entered 'No (N)'	System	08 Sep 2020 02:36:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:10

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:35:55', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1a0faf01-c85c-4a67-9122-d8f0260f4876'	System	08 Sep 2020 02:36:36
User entered '07 Sep 2020 22:35'	System	08 Sep 2020 02:36:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:07
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:05:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 19:34:15

US3352299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:07
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:05:39
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 19:34:15

US3352299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:07
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:05:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Sep 2020 19:34:15

US3352299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:07
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:05:39
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 19:34:15

US3352299

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:07
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:05:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 19:34:28

US3352299
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:13:10
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:07
User entered '1'	System	08 Sep 2020 19:34:28

US3352299
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:13:10

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:06:28
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	15 Sep 2020 19:27:31

US3352299
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:13:10
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:06:28
User entered '15 Sep 2020'	Sara Gomez (b) (4) (b) (4)	15 Sep 2020 19:27:31

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:06:28
User entered 'Contact Made (CONTACT MADE)'	Sara Gomez (b) (4) (b) (4)	15 Sep 2020 19:27:31

US3352299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:06:28
User entered empty.	Sara Gomez (b) (4) (b) (4)	15 Sep 2020 19:27:31

US3352299

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'Please enter the data for Day 22 per source visit was conducted on 23-Sep-2020' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 19:02:11
Query 'Please enter the data for Day 22 per source visit was conducted on 23-Sep-2020' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	30 Dec 2020 20:34:36
User opened query 'Please enter the data for Day 22 per source visit was conducted on 23-Sep-2020' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 15:08:00
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:06:32
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	15 Sep 2020 19:27:37

US3352299
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:13:10
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User entered '1'	System	15 Sep 2020 19:27:37

US3352299
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:13:10

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:42:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 20:34:28

US3352299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:52:00
User closed query 'Please clarify, per source this is 23-Sep-2020.' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 03:28:56
Query 'Please clarify, per source this is 23-Sep-2020.' answered with 'Data updated ' (Site from CRA).	Wanda Delgado (b) (4)	17 Feb 2021 16:22:26
DataPoint Un-verified.	Wanda Delgado (b) (4)	17 Feb 2021 16:22:01
User entered '23 Sep 2020' reason for change: Data Entry Error	Wanda Delgado (b) (4)	17 Feb 2021 16:22:01
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:42:27
DataPoint Un-verified.		09 Feb 2021 15:42:22
DataPoint Verified.		09 Feb 2021 15:42:19
User opened query 'Please clarify, per source this is 23-Sep-2020.' (Site from CRA).		09 Feb 2021 15:42:15
User entered '22 Sep 2020'		30 Dec 2020 20:34:28

US3352299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:42:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Dec 2020 20:34:28

US3352299
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:13:10
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:42:19
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 20:34:28

US3352299

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:42:37
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 14:10:14

US3352299

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:24
User entered '1'	System	29 Sep 2020 14:10:14

US3352299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:10

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:41:44
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	29 Sep 2020 15:05:41

US3352299
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:13:10

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:41:44
User entered '29 Sep 2020'	Wanda Delgado (b) (4)	29 Sep 2020 15:05:41

US3352299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:41:44
User entered 'Clinic (Clinic)'	Wanda Delgado (b) (4)	29 Sep 2020 15:05:41

US3352299
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:13:10
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User entered 'VISIT2'	System	29 Sep 2020 15:05:41

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User accepted default value 'Pre-Dose (PREDOSE)'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered '29 Sep 2020'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered '09:10'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User entered '29 Sep 2020 09:10'	System	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered '97.6' F	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered 'Oral (Oral)'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered empty.	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered '56'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User entered 'bpm'	System	29 Sep 2020 15:06:54

FDA-CBER-2022-1614-0965485

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered '14'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User entered 'breaths/min'	System	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered '129'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User entered 'mmHg'	System	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered '83'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User entered 'mmHg'	System	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User accepted default value 'Post-Dose (POSTDOSE)'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered '29 Sep 2020'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered '10:25'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User entered '29 Sep 2020 10:25'	System	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered '36.8' C	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered 'Oral (Oral)'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered empty.	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

US3352299
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:13:10

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered '51'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User entered 'bpm'	System	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered '13'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User entered 'breaths/min'	System	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered '125'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User entered 'mmHg'	System	29 Sep 2020 15:06:54

FDA-CBER-2022-1614-0965505

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:02
User entered '78'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User entered 'mmHg'	System	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:10

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:24
User entered 'No (N)'	Wanda Delgado (b) (4)	29 Sep 2020 15:07:24

US3352299

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:10

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:43:24
User entered empty.	Wanda Delgado (b) (4)	29 Sep 2020 15:07:24

US3352299
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:13:10
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:44:09
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 14:10:46

US3352299
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:13:10
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:44:09
User entered empty.	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 14:10:46

US3352299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:10

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)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:44:09
User entered empty.	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 14:10:46

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 14:10:46

US3352299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:10

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:44:09
User entered '29 Sep 2020'	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 14:10:46

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:44:09
User entered '09:55'	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 14:10:46

US3352299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:10

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User entered '29 Sep 2020 09:55'	System	29 Sep 2020 14:10:46

US3352299
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:13:10
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:44:09
User entered 'Left Arm (LEFT ARM)'	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 14:10:46

US3352299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:10

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:44:09
User entered 'ONCE'	System	29 Sep 2020 14:10:46

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:13:10
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 14:10:46

US3352299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:10

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:44:19
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	29 Sep 2020 15:07:39

US3352299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:10

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:44:19
User entered '29 Sep 2020'	Wanda Delgado (b) (4)	29 Sep 2020 15:07:39

US3352299
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:13:10
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:44:19
User entered '09:29'	Wanda Delgado (b) (4)	29 Sep 2020 15:07:39

US3352299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:10

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User entered '29 Sep 2020 09:29'	System	29 Sep 2020 15:07:39

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:13:10

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:44:58
User entered '29 Sep 2020'	Wanda Delgado (b) (4)	29 Sep 2020 15:07:56

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:10

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Wanda Delgado (b) (4)	29 Sep 2020 15:07:56

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:10

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:44:58
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	29 Sep 2020 15:07:56

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:44:58
User entered '09:24'	Wanda Delgado (b) (4)	29 Sep 2020 15:07:56

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:10

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User entered '29 Sep 2020 09:24'	System	29 Sep 2020 15:07:56

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:10

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Wanda Delgado (b) (4)	29 Sep 2020 15:07:56

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:10

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:44:58
User entered 'No (N)'	Wanda Delgado (b) (4)	29 Sep 2020 15:07:56

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:44:58
User entered empty.	Wanda Delgado (b) (4)	29 Sep 2020 15:07:56

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User entered empty.	System	29 Sep 2020 15:07:56

US3352299

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:45:08
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	29 Sep 2020 15:08:03

US3352299
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:13:10
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:22
User entered '1'	System	29 Sep 2020 15:08:03

US3352299
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:28:31', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '6accf5eb-db54-4755-89de-e289205c560b'	System	29 Sep 2020 14:28:45
User entered 'Yes (Y)'	System	29 Sep 2020 14:28:45

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:28:35', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '6accf5eb-db54-4755-89de-e289205c560b'	System	29 Sep 2020 14:28:45
User entered '98.3'	System	29 Sep 2020 14:28:45

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:28:39', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '6accf5eb-db54-4755-89de-e289205c560b'	System	29 Sep 2020 14:28:45
User entered 'No (N)'	System	29 Sep 2020 14:28:45

US3352299
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:28:42', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '6accf5eb-db54-4755-89de-e289205c560b'	System	29 Sep 2020 14:28:45
User entered '29 Sep 2020 10:28'	System	29 Sep 2020 14:28:45

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '29 Sep 2020 10:15'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '29 Sep 2020 12:45'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:37:03', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '3c34a680-9ac9-4e03-b1e6-08e69ab31130'	System	29 Sep 2020 23:37:15
User entered 'Yes (Y)'	System	29 Sep 2020 23:37:15

US3352299
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:13:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:37:07', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '3c34a680-9ac9-4e03-b1e6-08e69ab31130'	System	29 Sep 2020 23:37:15
User entered '96.2'	System	29 Sep 2020 23:37:15

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:37:10', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '3c34a680-9ac9-4e03-b1e6-08e69ab31130'	System	29 Sep 2020 23:37:15
User entered 'No (N)'	System	29 Sep 2020 23:37:15

US3352299
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:13:10
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:37:13', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '3c34a680-9ac9-4e03-b1e6-08e69ab31130'	System	29 Sep 2020 23:37:15
User entered '29 Sep 2020 19:37'	System	29 Sep 2020 23:37:15

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '29 Sep 2020 13:40'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 2'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:53:22', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a65cf7e2-380e-459e-93ea-345b5d0c89e8'	System	30 Sep 2020 22:53:36
User entered 'Yes (Y)'	System	30 Sep 2020 22:53:36

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:53:27', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a65cf7e2-380e-459e-93ea-345b5d0c89e8'	System	30 Sep 2020 22:53:36
User entered '101.0'	System	30 Sep 2020 22:53:36

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:53:30', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a65cf7e2-380e-459e-93ea-345b5d0c89e8'	System	30 Sep 2020 22:53:36
User entered 'No (N)'	System	30 Sep 2020 22:53:36

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:10

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:53:35', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a65cf7e2-380e-459e-93ea-345b5d0c89e8'	System	30 Sep 2020 22:53:36
User entered '30 Sep 2020 18:53'	System	30 Sep 2020 22:53:36

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 3'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:27:48', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7a323f96-8e74-44b7-801a-8a320b970e8a'	System	02 Oct 2020 00:28:02
User entered 'Yes (Y)'	System	02 Oct 2020 00:28:02

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:27:53', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7a323f96-8e74-44b7-801a-8a320b970e8a'	System	02 Oct 2020 00:28:02
User entered '98.2'	System	02 Oct 2020 00:28:02

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:27:56', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7a323f96-8e74-44b7-801a-8a320b970e8a'	System	02 Oct 2020 00:28:02
User entered 'No (N)'	System	02 Oct 2020 00:28:02

FDA-CBER-2022-1614-0965559

US3352299
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:13:10
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:27:59', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7a323f96-8e74-44b7-801a-8a320b970e8a'	System	02 Oct 2020 00:28:02
User entered '01 Oct 2020 20:27'	System	02 Oct 2020 00:28:02

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:13:10
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 4'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:13:10
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:20', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5bc60b06-7b90-46dc-8208-141ce1a286cd'	System	03 Oct 2020 16:13:44
User entered 'Yes (Y)'	System	03 Oct 2020 16:13:44

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:24', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5bc60b06-7b90-46dc-8208-141ce1a286cd'	System	03 Oct 2020 16:13:44
User entered '98.2'	System	03 Oct 2020 16:13:44

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:27', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5bc60b06-7b90-46dc-8208-141ce1a286cd'	System	03 Oct 2020 16:13:44
User entered 'No (N)'	System	03 Oct 2020 16:13:44

US3352299
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:13:10
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:30', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5bc60b06-7b90-46dc-8208-141ce1a286cd'	System	03 Oct 2020 16:13:44
User entered '03 Oct 2020 06:52'	System	03 Oct 2020 16:13:44

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 5'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:12:50', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4e1aa54e-61fb-474c-bf20-fc2c6f51c4e4'	System	03 Oct 2020 16:13:48
User entered 'Yes (Y)'	System	03 Oct 2020 16:13:48

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:12:53', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4e1aa54e-61fb-474c-bf20-fc2c6f51c4e4'	System	03 Oct 2020 16:13:48
User entered '97.9'	System	03 Oct 2020 16:13:48

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:12:56', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4e1aa54e-61fb-474c-bf20-fc2c6f51c4e4'	System	03 Oct 2020 16:13:48
User entered 'No (N)'	System	03 Oct 2020 16:13:48

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:10

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:12:58', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4e1aa54e-61fb-474c-bf20-fc2c6f51c4e4'	System	03 Oct 2020 16:13:48
User entered '03 Oct 2020 12:12'	System	03 Oct 2020 16:13:48

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 6'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:01:40', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'bfc16047-6df7-411a-9892-339abdcff4e5'	System	05 Oct 2020 11:01:53
User entered 'Yes (Y)'	System	05 Oct 2020 11:01:53

US3352299
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:13:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:01:44', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'bfc16047-6df7-411a-9892-339abdcff4e5'	System	05 Oct 2020 11:01:53
User entered '97.6'	System	05 Oct 2020 11:01:53

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:01:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'bfc16047-6df7-411a-9892-339abdcff4e5'	System	05 Oct 2020 11:01:53
User entered 'No (N)'	System	05 Oct 2020 11:01:53

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:10

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:01:50', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'bfc16047-6df7-411a-9892-339abdcff4e5'	System	05 Oct 2020 11:01:53
User entered '05 Oct 2020 07:01'	System	05 Oct 2020 11:01:53

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 7'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:34:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7b35ddfb-83b3-48dd-bb24-0bf203e8f6cb'	System	05 Oct 2020 21:35:36
User entered 'Yes (Y)'	System	05 Oct 2020 21:35:36

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:34:51', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7b35ddfb-83b3-48dd-bb24-0bf203e8f6cb'	System	05 Oct 2020 21:35:36
User entered '98.2'	System	05 Oct 2020 21:35:36

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:35:14', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7b35ddfb-83b3-48dd-bb24-0bf203e8f6cb'	System	05 Oct 2020 21:35:36
User entered 'No (N)'	System	05 Oct 2020 21:35:36

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:10

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:35:26', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7b35ddfb-83b3-48dd-bb24-0bf203e8f6cb'	System	05 Oct 2020 21:35:36
User entered '05 Oct 2020 17:35'	System	05 Oct 2020 21:35:36

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:28:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8f3d0fa9-b3c3-40d8-b9b7-87e274a8fde2'	System	29 Sep 2020 14:29:02
User entered 'None (1)'	System	29 Sep 2020 14:29:02

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:28:50', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8f3d0fa9-b3c3-40d8-b9b7-87e274a8fde2'	System	29 Sep 2020 14:29:02
User entered 'No (N)'	System	29 Sep 2020 14:29:02

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:28:52', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8f3d0fa9-b3c3-40d8-b9b7-87e274a8fde2'	System	29 Sep 2020 14:29:02
User entered 'No (N)'	System	29 Sep 2020 14:29:02

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:28:56', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8f3d0fa9-b3c3-40d8-b9b7-87e274a8fde2'	System	29 Sep 2020 14:29:02
User entered 'None (1)'	System	29 Sep 2020 14:29:02

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:28:59', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8f3d0fa9-b3c3-40d8-b9b7-87e274a8fde2'	System	29 Sep 2020 14:29:02
User entered '29 Sep 2020 10:28'	System	29 Sep 2020 14:29:02

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '29 Sep 2020 10:15'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '29 Sep 2020 12:45'	System	29 Sep 2020 14:10:46

Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:37:24', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'b1ae49b2-cd73-42b1-bbab-e0b08e77e168'	System	29 Sep 2020 23:37:59
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 23:37:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:37:36', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'b1ae49b2-cd73-42b1-bbab-e0b08e77e168'	System	29 Sep 2020 23:37:59
User entered 'No (N)'	System	29 Sep 2020 23:37:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:37:44', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'b1ae49b2-cd73-42b1-bbab-e0b08e77e168'	System	29 Sep 2020 23:37:59
User entered 'No (N)'	System	29 Sep 2020 23:37:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:37:53', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'b1ae49b2-cd73-42b1-bbab-e0b08e77e168'	System	29 Sep 2020 23:37:59
User entered 'None (1)'	System	29 Sep 2020 23:37:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:37:56', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'b1ae49b2-cd73-42b1-bbab-e0b08e77e168'	System	29 Sep 2020 23:37:59
User entered '29 Sep 2020 19:37'	System	29 Sep 2020 23:37:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '29 Sep 2020 13:40'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:13:10
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:10:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 2'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:53:41', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5b1c44bd-2f50-4216-9f87-3f0f923348cf'	System	30 Sep 2020 22:53:58
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 22:53:58

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:53:43', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5b1c44bd-2f50-4216-9f87-3f0f923348cf'	System	30 Sep 2020 22:53:58
User entered 'No (N)'	System	30 Sep 2020 22:53:58

FDA-CBER-2022-1614-0965609

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:53:46', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5b1c44bd-2f50-4216-9f87-3f0f923348cf'	System	30 Sep 2020 22:53:58
User entered 'No (N)'	System	30 Sep 2020 22:53:58

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:53:51', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5b1c44bd-2f50-4216-9f87-3f0f923348cf'	System	30 Sep 2020 22:53:58
User entered 'None (1)'	System	30 Sep 2020 22:53:58

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:13:10
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:53:55', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5b1c44bd-2f50-4216-9f87-3f0f923348cf'	System	30 Sep 2020 22:53:58
User entered '30 Sep 2020 18:53'	System	30 Sep 2020 22:53:58

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:13:10
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:13:10
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 3'	System	29 Sep 2020 14:10:46

FDA-CBER-2022-1614-0965615

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:06', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '43124511-99b1-4d71-9cfa-6d60ae32d294'	System	02 Oct 2020 00:28:18
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 00:28:18

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:08', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '43124511-99b1-4d71-9cfa-6d60ae32d294'	System	02 Oct 2020 00:28:18
User entered 'No (N)'	System	02 Oct 2020 00:28:18

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:11', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '43124511-99b1-4d71-9cfa-6d60ae32d294'	System	02 Oct 2020 00:28:18
User entered 'No (N)'	System	02 Oct 2020 00:28:18

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:15', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '43124511-99b1-4d71-9cfa-6d60ae32d294'	System	02 Oct 2020 00:28:18
User entered 'None (1)'	System	02 Oct 2020 00:28:18

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:13:10
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:17', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '43124511-99b1-4d71-9cfa-6d60ae32d294'	System	02 Oct 2020 00:28:18
User entered '01 Oct 2020 20:28'	System	02 Oct 2020 00:28:18

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 4'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:38', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '68b7e188-6817-4dc2-9d3e-795fffdaec77'	System	03 Oct 2020 16:13:44
User entered 'None (1)'	System	03 Oct 2020 16:13:44

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:13:10
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:41', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '68b7e188-6817-4dc2-9d3e-795fffdaec77'	System	03 Oct 2020 16:13:44
User entered 'No (N)'	System	03 Oct 2020 16:13:44

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:43', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '68b7e188-6817-4dc2-9d3e-795fffdaec77'	System	03 Oct 2020 16:13:44
User entered 'No (N)'	System	03 Oct 2020 16:13:44

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:45', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '68b7e188-6817-4dc2-9d3e-795fffdaec77'	System	03 Oct 2020 16:13:44
User entered 'None (1)'	System	03 Oct 2020 16:13:44

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:10

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:48', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '68b7e188-6817-4dc2-9d3e-795fffdaec77'	System	03 Oct 2020 16:13:44
User entered '03 Oct 2020 06:52'	System	03 Oct 2020 16:13:44

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:13:10
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 5'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:07', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8c04e52c-04e1-431d-842c-3d94d5db4d9a'	System	03 Oct 2020 16:13:59
User entered 'None (1)'	System	03 Oct 2020 16:13:59

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:13:10
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:06', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8c04e52c-04e1-431d-842c-3d94d5db4d9a'	System	03 Oct 2020 16:13:59
User entered 'No (N)'	System	03 Oct 2020 16:13:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:10', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8c04e52c-04e1-431d-842c-3d94d5db4d9a'	System	03 Oct 2020 16:13:59
User entered 'No (N)'	System	03 Oct 2020 16:13:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:12', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8c04e52c-04e1-431d-842c-3d94d5db4d9a'	System	03 Oct 2020 16:13:59
User entered 'None (1)'	System	03 Oct 2020 16:13:59

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:13:10
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:14', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8c04e52c-04e1-431d-842c-3d94d5db4d9a'	System	03 Oct 2020 16:13:59
User entered '03 Oct 2020 12:13'	System	03 Oct 2020 16:13:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:13:10
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 6'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:01:54', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7d2f8537-40c8-4532-956b-32630004e37e'	System	05 Oct 2020 11:02:08
User entered 'None (1)'	System	05 Oct 2020 11:02:08

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:01:56', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7d2f8537-40c8-4532-956b-32630004e37e'	System	05 Oct 2020 11:02:08
User entered 'No (N)'	System	05 Oct 2020 11:02:08

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7d2f8537-40c8-4532-956b-32630004e37e'	System	05 Oct 2020 11:02:08
User entered 'No (N)'	System	05 Oct 2020 11:02:08

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:02', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7d2f8537-40c8-4532-956b-32630004e37e'	System	05 Oct 2020 11:02:08
User entered 'None (1)'	System	05 Oct 2020 11:02:08

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:13:10
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:04', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7d2f8537-40c8-4532-956b-32630004e37e'	System	05 Oct 2020 11:02:08
User entered '05 Oct 2020 07:02'	System	05 Oct 2020 11:02:08

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 7'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:35:51', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '0598af45-c5f9-4158-a610-02c522fbb659'	System	05 Oct 2020 21:36:13
User entered 'None (1)'	System	05 Oct 2020 21:36:13

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:13:10
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:35:54', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '0598af45-c5f9-4158-a610-02c522fbb659'	System	05 Oct 2020 21:36:13
User entered 'No (N)'	System	05 Oct 2020 21:36:13

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:13:10
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:02', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '0598af45-c5f9-4158-a610-02c522fbb659'	System	05 Oct 2020 21:36:13
User entered 'No (N)'	System	05 Oct 2020 21:36:13

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:05', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '0598af45-c5f9-4158-a610-02c522fbb659'	System	05 Oct 2020 21:36:13
User entered 'None (1)'	System	05 Oct 2020 21:36:13

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:13:10
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:11', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '0598af45-c5f9-4158-a610-02c522fbb659'	System	05 Oct 2020 21:36:13
User entered '05 Oct 2020 17:36'	System	05 Oct 2020 21:36:13

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:13:10
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:13:10
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:29:04', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '12f74c9d-0e8d-4868-a53b-e78bf9067f40'	System	29 Sep 2020 14:29:22
User entered 'None (0)'	System	29 Sep 2020 14:29:22

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:29:06', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '12f74c9d-0e8d-4868-a53b-e78bf9067f40'	System	29 Sep 2020 14:29:22
User entered 'None (0)'	System	29 Sep 2020 14:29:22

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:29:09', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '12f74c9d-0e8d-4868-a53b-e78bf9067f40'	System	29 Sep 2020 14:29:22
User entered 'None (0)'	System	29 Sep 2020 14:29:22

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:29:10', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '12f74c9d-0e8d-4868-a53b-e78bf9067f40'	System	29 Sep 2020 14:29:22
User entered 'None (0)'	System	29 Sep 2020 14:29:22

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:29:12', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '12f74c9d-0e8d-4868-a53b-e78bf9067f40'	System	29 Sep 2020 14:29:22
User entered 'None (0)'	System	29 Sep 2020 14:29:22

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:13:10
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:29:13', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '12f74c9d-0e8d-4868-a53b-e78bf9067f40'	System	29 Sep 2020 14:29:22
User entered 'None (0)'	System	29 Sep 2020 14:29:22

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:29:17', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '12f74c9d-0e8d-4868-a53b-e78bf9067f40'	System	29 Sep 2020 14:29:22
User entered 'No (N)'	System	29 Sep 2020 14:29:22

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:29:19', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '12f74c9d-0e8d-4868-a53b-e78bf9067f40'	System	29 Sep 2020 14:29:22
User entered '29 Sep 2020 10:29'	System	29 Sep 2020 14:29:22

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '29 Sep 2020 10:15'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '29 Sep 2020 12:45'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:13:10
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:38:02', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '08d03193-fb2b-427e-af61-f8a039104293'	System	29 Sep 2020 23:38:24
User entered 'None (0)'	System	29 Sep 2020 23:38:24

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:13:10
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:38:05', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '08d03193-fb2b-427e-af61-f8a039104293'	System	29 Sep 2020 23:38:24
User entered 'None (0)'	System	29 Sep 2020 23:38:24

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:38:08', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '08d03193-fb2b-427e-af61-f8a039104293'	System	29 Sep 2020 23:38:24
User entered 'None (0)'	System	29 Sep 2020 23:38:24

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:13:10
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:38:10', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '08d03193-fb2b-427e-af61-f8a039104293'	System	29 Sep 2020 23:38:24
User entered 'None (0)'	System	29 Sep 2020 23:38:24

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:38:12', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '08d03193-fb2b-427e-af61-f8a039104293'	System	29 Sep 2020 23:38:24
User entered 'None (0)'	System	29 Sep 2020 23:38:24

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:13:10
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:38:15', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '08d03193-fb2b-427e-af61-f8a039104293'	System	29 Sep 2020 23:38:24
User entered 'No interference with activity (1)'	System	29 Sep 2020 23:38:24

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:38:18', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '08d03193-fb2b-427e-af61-f8a039104293'	System	29 Sep 2020 23:38:24
User entered 'No (N)'	System	29 Sep 2020 23:38:24

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:38:20', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '08d03193-fb2b-427e-af61-f8a039104293'	System	29 Sep 2020 23:38:24
User entered '29 Sep 2020 19:38'	System	29 Sep 2020 23:38:24

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '29 Sep 2020 13:40'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 2'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:13:10
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:54:27', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '22a0b529-f254-4a56-9348-efd504fa9b08'	System	30 Sep 2020 22:55:05
User entered 'No interference with activity (1)'	System	30 Sep 2020 22:55:05

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:13:10
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:54:40', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '22a0b529-f254-4a56-9348-efd504fa9b08'	System	30 Sep 2020 22:55:05
User entered 'Some interference with activity (2)'	System	30 Sep 2020 22:55:05

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:13:10
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:54:45', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '22a0b529-f254-4a56-9348-efd504fa9b08'	System	30 Sep 2020 22:55:05
User entered 'None (0)'	System	30 Sep 2020 22:55:05

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:13:10
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:54:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '22a0b529-f254-4a56-9348-efd504fa9b08'	System	30 Sep 2020 22:55:05
User entered 'None (0)'	System	30 Sep 2020 22:55:05

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:13:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:54:50', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '22a0b529-f254-4a56-9348-efd504fa9b08'	System	30 Sep 2020 22:55:05
User entered 'None (0)'	System	30 Sep 2020 22:55:05

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:13:10
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:54:55', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '22a0b529-f254-4a56-9348-efd504fa9b08'	System	30 Sep 2020 22:55:05
User entered 'Some interference with activity not requiring medical attention (2)'	System	30 Sep 2020 22:55:05

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:54:59', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '22a0b529-f254-4a56-9348-efd504fa9b08'	System	30 Sep 2020 22:55:05
User entered 'No (N)'	System	30 Sep 2020 22:55:05

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:10

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:55:01', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '22a0b529-f254-4a56-9348-efd504fa9b08'	System	30 Sep 2020 22:55:05
User entered '30 Sep 2020 18:55'	System	30 Sep 2020 22:55:05

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 3'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:13:10
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:22', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '336f9d45-4b04-4852-94d9-6825eecccaa2'	System	02 Oct 2020 00:28:43
User entered 'No interference with activity (1)'	System	02 Oct 2020 00:28:43

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:13:10
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:24', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '336f9d45-4b04-4852-94d9-6825eecccaa2'	System	02 Oct 2020 00:28:43
User entered 'No interference with activity (1)'	System	02 Oct 2020 00:28:43

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:13:10
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:27', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '336f9d45-4b04-4852-94d9-6825eecccaa2'	System	02 Oct 2020 00:28:43
User entered 'None (0)'	System	02 Oct 2020 00:28:43

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:13:10
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:29', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '336f9d45-4b04-4852-94d9-6825eecccaa2'	System	02 Oct 2020 00:28:43
User entered 'None (0)'	System	02 Oct 2020 00:28:43

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:13:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:31', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '336f9d45-4b04-4852-94d9-6825eecccaa2'	System	02 Oct 2020 00:28:43
User entered 'None (0)'	System	02 Oct 2020 00:28:43

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:13:10
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:34', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '336f9d45-4b04-4852-94d9-6825eecccaa2'	System	02 Oct 2020 00:28:43
User entered 'No interference with activity (1)'	System	02 Oct 2020 00:28:43

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:36', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '336f9d45-4b04-4852-94d9-6825eecccaa2'	System	02 Oct 2020 00:28:43
User entered 'No (N)'	System	02 Oct 2020 00:28:43

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:10

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:39', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '336f9d45-4b04-4852-94d9-6825eecccaa2'	System	02 Oct 2020 00:28:43
User entered '01 Oct 2020 20:28'	System	02 Oct 2020 00:28:43

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 4'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:13:10
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:55', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd1724943-aa3a-4d0f-bf33-203f67f4d934'	System	03 Oct 2020 16:13:45
User entered 'None (0)'	System	03 Oct 2020 16:13:45

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:13:10
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:57', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd1724943-aa3a-4d0f-bf33-203f67f4d934'	System	03 Oct 2020 16:13:45
User entered 'None (0)'	System	03 Oct 2020 16:13:45

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:13:10
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:59', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd1724943-aa3a-4d0f-bf33-203f67f4d934'	System	03 Oct 2020 16:13:45
User entered 'None (0)'	System	03 Oct 2020 16:13:45

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:13:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:53:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd1724943-aa3a-4d0f-bf33-203f67f4d934'	System	03 Oct 2020 16:13:45
User entered 'None (0)'	System	03 Oct 2020 16:13:45

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:13:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:53:02', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd1724943-aa3a-4d0f-bf33-203f67f4d934'	System	03 Oct 2020 16:13:45
User entered 'None (0)'	System	03 Oct 2020 16:13:45

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:13:10
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:53:03', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd1724943-aa3a-4d0f-bf33-203f67f4d934'	System	03 Oct 2020 16:13:45
User entered 'None (0)'	System	03 Oct 2020 16:13:45

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:53:05', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd1724943-aa3a-4d0f-bf33-203f67f4d934'	System	03 Oct 2020 16:13:45
User entered 'No (N)'	System	03 Oct 2020 16:13:45

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:13:10

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:53:08', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd1724943-aa3a-4d0f-bf33-203f67f4d934'	System	03 Oct 2020 16:13:45
User entered '03 Oct 2020 06:53'	System	03 Oct 2020 16:13:45

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 5'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:13:10
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:20', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ed79f053-320d-461c-9066-2668cfcce91c'	System	03 Oct 2020 16:14:11
User entered 'No interference with activity (1)'	System	03 Oct 2020 16:14:11

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:13:10
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:23', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ed79f053-320d-461c-9066-2668cfcce91c'	System	03 Oct 2020 16:14:11
User entered 'No interference with activity (1)'	System	03 Oct 2020 16:14:11

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:13:10
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:25', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ed79f053-320d-461c-9066-2668cfcce91c'	System	03 Oct 2020 16:14:11
User entered 'None (0)'	System	03 Oct 2020 16:14:11

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:13:10
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:27', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ed79f053-320d-461c-9066-2668cfcce91c'	System	03 Oct 2020 16:14:11
User entered 'None (0)'	System	03 Oct 2020 16:14:11

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:13:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:29', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ed79f053-320d-461c-9066-2668cfcce91c'	System	03 Oct 2020 16:14:11
User entered 'None (0)'	System	03 Oct 2020 16:14:11

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:13:10
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:30', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ed79f053-320d-461c-9066-2668cfcce91c'	System	03 Oct 2020 16:14:11
User entered 'None (0)'	System	03 Oct 2020 16:14:11

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:33', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ed79f053-320d-461c-9066-2668cfcce91c'	System	03 Oct 2020 16:14:11
User entered 'No (N)'	System	03 Oct 2020 16:14:11

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:10

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:36', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ed79f053-320d-461c-9066-2668cfcce91c'	System	03 Oct 2020 16:14:11
User entered '03 Oct 2020 12:13'	System	03 Oct 2020 16:14:11

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 6'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:13:10
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:08', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'be483b46-07d4-4379-9762-4520863519c8'	System	05 Oct 2020 11:02:27
User entered 'None (0)'	System	05 Oct 2020 11:02:27

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:13:10
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:10', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'be483b46-07d4-4379-9762-4520863519c8'	System	05 Oct 2020 11:02:27
User entered 'None (0)'	System	05 Oct 2020 11:02:27

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:13:10
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:12', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'be483b46-07d4-4379-9762-4520863519c8'	System	05 Oct 2020 11:02:27
User entered 'None (0)'	System	05 Oct 2020 11:02:27

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:13:10
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:16', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'be483b46-07d4-4379-9762-4520863519c8'	System	05 Oct 2020 11:02:27
User entered 'None (0)'	System	05 Oct 2020 11:02:27

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:13:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:18', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'be483b46-07d4-4379-9762-4520863519c8'	System	05 Oct 2020 11:02:27
User entered 'None (0)'	System	05 Oct 2020 11:02:27

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:13:10
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:19', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'be483b46-07d4-4379-9762-4520863519c8'	System	05 Oct 2020 11:02:27
User entered 'None (0)'	System	05 Oct 2020 11:02:27

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:23', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'be483b46-07d4-4379-9762-4520863519c8'	System	05 Oct 2020 11:02:27
User entered 'No (N)'	System	05 Oct 2020 11:02:27

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:10

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:26', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'be483b46-07d4-4379-9762-4520863519c8'	System	05 Oct 2020 11:02:27
User entered '05 Oct 2020 07:02'	System	05 Oct 2020 11:02:27

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 7'	System	29 Sep 2020 14:10:46

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:13:10
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:25', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f67eddf5-54c1-494d-8312-9f108b79fefe'	System	05 Oct 2020 21:36:50
User entered 'None (0)'	System	05 Oct 2020 21:36:50

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:13:10
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:26', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f67eddf5-54c1-494d-8312-9f108b79fefe'	System	05 Oct 2020 21:36:50
User entered 'None (0)'	System	05 Oct 2020 21:36:50

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:32', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f67eddf5-54c1-494d-8312-9f108b79fefe'	System	05 Oct 2020 21:36:50
User entered 'None (0)'	System	05 Oct 2020 21:36:50

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:13:10
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:33', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f67eddf5-54c1-494d-8312-9f108b79fefe'	System	05 Oct 2020 21:36:50
User entered 'None (0)'	System	05 Oct 2020 21:36:50

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:13:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:37', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f67eddf5-54c1-494d-8312-9f108b79fefe'	System	05 Oct 2020 21:36:50
User entered 'None (0)'	System	05 Oct 2020 21:36:50

US3352299
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:13:10
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:39', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f67eddf5-54c1-494d-8312-9f108b79fefe'	System	05 Oct 2020 21:36:50
User entered 'None (0)'	System	05 Oct 2020 21:36:50

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:44', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f67eddf5-54c1-494d-8312-9f108b79fefe'	System	05 Oct 2020 21:36:50
User entered 'No (N)'	System	05 Oct 2020 21:36:50

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:10

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:46', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f67eddf5-54c1-494d-8312-9f108b79fefe'	System	05 Oct 2020 21:36:50
User entered '05 Oct 2020 17:36'	System	05 Oct 2020 21:36:50

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:10

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:17:42
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:21:50
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	06 Oct 2020 13:44:31

US3352299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:17:42
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:21:50
User entered '6 Oct 2020'	Yulexis Amestoy (b) (4) (b) (4)	06 Oct 2020 13:44:31

US3352299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:17:42
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:21:50
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4) (b) (4)	06 Oct 2020 13:44:31

US3352299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:17:42
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:21:50
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	06 Oct 2020 13:44:31

US3352299

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:17:42
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:21:56
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	06 Oct 2020 13:44:36

US3352299

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:17:42
User entered '1'	System	06 Oct 2020 13:44:36

US3352299
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:13:10

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:23:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 21:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:23:17
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 21:12:27

US3352299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:23:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 21:12:27

US3352299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:23:17
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 21:12:27

US3352299

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:23:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 21:12:31

US3352299

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:47
User entered '1'	System	14 Oct 2020 21:12:31

US3352299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:20:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:23:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 19:18:58

US3352299
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:20:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:23:52
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 19:18:58

US3352299
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:13:10
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:20:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:23:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Oct 2020 19:18:58

US3352299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:20:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:23:52
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:18:58

US3352299

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:20:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:25:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 19:19:35

US3352299

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:20:48
User entered '1'	System	20 Oct 2020 19:19:35

US3352299
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:13:10
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:45:52
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	27 Oct 2020 13:57:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:45:52
User entered '27 Oct 2020'	Matthew Muniz (b) (4)	27 Oct 2020 13:57:32

US3352299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:45:52
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	27 Oct 2020 13:57:32

US3352299
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:13:10
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User entered 'VISIT3'	System	27 Oct 2020 13:57:32

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:34:28
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:34:28
User entered '27 Oct 2020'	Matthew Muniz (b) (4)	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:34:28
User entered '09:16'	Matthew Muniz (b) (4)	27 Oct 2020 13:58:11

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User entered '27 Oct 2020 09:16'	System	27 Oct 2020 13:58:11

FDA-CBER-2022-1614-0965768

US3352299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:34:28
User entered '36.6' C	Matthew Muniz (b) (4)	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:34:28
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	27 Oct 2020 13:58:11

US3352299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:34:28
User entered empty.	Matthew Muniz (b) (4)	27 Oct 2020 13:58:11

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:34:28
User entered '48' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4) (b) (4)	19 Apr 2021 20:33:34
User entered '98'	Matthew Muniz (b) (4)	27 Oct 2020 13:58:11

US3352299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User entered 'bpm'	System	27 Oct 2020 13:58:11

US3352299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:34:28
User entered '14'	Matthew Muniz (b) (4)	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User entered 'breaths/min'	System	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:34:28
User entered '121'	Matthew Muniz (b) (4)	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User entered 'mmHg'	System	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:34:28
User entered '71'	Matthew Muniz (b) (4)	27 Oct 2020 13:58:11

US3352299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User entered 'mmHg'	System	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13

US3352299

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:10

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:49:36
User entered 'No (N)'	Matthew Muniz (b) (4)	27 Oct 2020 13:58:15

US3352299

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:10

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:49:36
User entered empty.	Matthew Muniz (b) (4)	27 Oct 2020 13:58:15

US3352299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:10

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:49:51
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	27 Oct 2020 13:58:24

US3352299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:10

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:49:51
User entered '27 Oct 2020'	Matthew Muniz (b) (4)	27 Oct 2020 13:58:24

US3352299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:49:51
User entered '09:30'	Matthew Muniz (b) (4)	27 Oct 2020 13:58:24

US3352299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:10

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User entered '27 Oct 2020 09:30'	System	27 Oct 2020 13:58:24

US3352299

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:49:57
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	27 Oct 2020 13:58:27

US3352299

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:13
User entered '1'	System	27 Oct 2020 13:58:27

US3352299
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 64'	System	01 Sep 2020 16:23:24

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-01T07:34:25', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7ad5b9c4-be94-4d67-948f-ba752d305f4b'	System	01 Nov 2020 12:34:40
User entered 'No (N)'	System	01 Nov 2020 12:34:40

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-01T07:34:33', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7ad5b9c4-be94-4d67-948f-ba752d305f4b'	System	01 Nov 2020 12:34:40
User entered 'No (N)'	System	01 Nov 2020 12:34:40

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-01T07:34:37', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7ad5b9c4-be94-4d67-948f-ba752d305f4b'	System	01 Nov 2020 12:34:40
User entered '01 Nov 2020 07:34:37'	System	01 Nov 2020 12:34:40

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 16:23:24

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 16:23:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 71'	System	01 Sep 2020 16:23:24

FDA-CBER-2022-1614-0965796

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-11T08:34:07', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd6fc9a5f-1cc4-4abf-9752-c8c65900743c'	System	11 Nov 2020 13:34:45
User entered 'Yes (Y)'	System	11 Nov 2020 13:34:45

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-11T08:34:13', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd6fc9a5f-1cc4-4abf-9752-c8c65900743c'	System	11 Nov 2020 13:34:45
User entered 'No (N)'	System	11 Nov 2020 13:34:45

FDA-CBER-2022-1614-0965798

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-11T08:34:18', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd6fc9a5f-1cc4-4abf-9752-c8c65900743c'	System	11 Nov 2020 13:34:45
User entered 'No (N)'	System	11 Nov 2020 13:34:45

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-11T08:34:24', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd6fc9a5f-1cc4-4abf-9752-c8c65900743c'	System	11 Nov 2020 13:34:45
User entered 'Yes (Y)'	System	11 Nov 2020 13:34:45

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-11T08:34:32', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd6fc9a5f-1cc4-4abf-9752-c8c65900743c'	System	11 Nov 2020 13:34:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Nov 2020 13:34:45

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-11T08:34:35', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd6fc9a5f-1cc4-4abf-9752-c8c65900743c'	System	11 Nov 2020 13:34:45
User entered '11 Nov 2020 08:34:35'	System	11 Nov 2020 13:34:45

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 16:23:24

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 16:23:24

Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 78'	System	01 Sep 2020 16:23:24

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-15T08:32:23', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '590b0f11-40d7-410e-bcb8-4b213057b18b'	System	15 Nov 2020 13:32:32
User entered 'No (N)'	System	15 Nov 2020 13:32:32

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-15T08:32:27', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '590b0f11-40d7-410e-bcb8-4b213057b18b'	System	15 Nov 2020 13:32:32
User entered 'No (N)'	System	15 Nov 2020 13:32:32

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-15T08:32:30', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '590b0f11-40d7-410e-bcb8-4b213057b18b'	System	15 Nov 2020 13:32:32
User entered '15 Nov 2020 08:32:30'	System	15 Nov 2020 13:32:32

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 16:23:24

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:23
Data entry locked.	System	01 Sep 2020 16:23:24
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-27T19:50:52', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '274ceaec-a56e-4a8d-ba1c-38d82e1ff5b4'	System	27 Nov 2020 22:51:03
User entered 'No (N)'	System	27 Nov 2020 22:51:03

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-27T19:50:57', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '274ceaec-a56e-4a8d-ba1c-38d82e1ff5b4'	System	27 Nov 2020 22:51:03
User entered 'No (N)'	System	27 Nov 2020 22:51:03

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-27T19:51:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '274ceaec-a56e-4a8d-ba1c-38d82e1ff5b4'	System	27 Nov 2020 22:51:03
User entered '27 Nov 2020 19:51:00'	System	27 Nov 2020 22:51:03

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:35:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10

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).	(b) (4), (b) (6)	08 Apr 2021 20:02:04
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 'yes response is related to AE # 5' (Site from DM).	Yulexis Amestoy (b) (4) (b) (4)	07 Apr 2021 15:03:53
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).	(b) (4), (b) (6)	28 Feb 2021 09:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-12-03T07:26:54', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '697329e1-37e5-4d02-8b33-7fae2c4d7060'	System	03 Dec 2020 12:27:34
User entered 'Yes (Y)'	System	03 Dec 2020 12:27:34

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-12-03T07:27:01', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '697329e1-37e5-4d02-8b33-7fae2c4d7060'	System	03 Dec 2020 12:27:34
User entered 'No (N)'	System	03 Dec 2020 12:27:34

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-12-03T07:27:13', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '697329e1-37e5-4d02-8b33-7fae2c4d7060'	System	03 Dec 2020 12:27:34
User entered 'No (N)'	System	03 Dec 2020 12:27:34

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-12-03T07:27:18', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '697329e1-37e5-4d02-8b33-7fae2c4d7060'	System	03 Dec 2020 12:27:34
User entered 'Yes (Y)'	System	03 Dec 2020 12:27:34

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Please 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-12-03T07:27:21', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '697329e1-37e5-4d02-8b33-7fae2c4d7060'	System	03 Dec 2020 12:27:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Dec 2020 12:27:34

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-12-03T07:27:24', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '697329e1-37e5-4d02-8b33-7fae2c4d7060'	System	03 Dec 2020 12:27:34
User entered '03 Dec 2020 07:27:24'	System	03 Dec 2020 12:27:34

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-12-10T19:42:13', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'dc1f8949-9945-48df-bada-2d3991e7a256'	System	11 Dec 2020 00:42:39
User entered 'No (N)'	System	11 Dec 2020 00:42:39

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-12-10T19:42:16', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'dc1f8949-9945-48df-bada-2d3991e7a256'	System	11 Dec 2020 00:42:39
User entered 'No (N)'	System	11 Dec 2020 00:42:39

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-12-10T19:42:34', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'dc1f8949-9945-48df-bada-2d3991e7a256'	System	11 Dec 2020 00:42:39
User entered '10 Dec 2020 19:42:34'	System	11 Dec 2020 00:42:39

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-12-17T13:18:30', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '6829c9df-17fc-4813-a8b9-77d16cdd0183'	System	17 Dec 2020 18:18:38
User entered 'No (N)'	System	17 Dec 2020 18:18:38

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-12-17T13:18:33', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '6829c9df-17fc-4813-a8b9-77d16cdd0183'	System	17 Dec 2020 18:18:38
User entered 'No (N)'	System	17 Dec 2020 18:18:38

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-12-17T13:18:36', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '6829c9df-17fc-4813-a8b9-77d16cdd0183'	System	17 Dec 2020 18:18:38
User entered '17 Dec 2020 13:18:36'	System	17 Dec 2020 18:18:38

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-12-24T12:11:07', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'e783e9a3-a2ae-48f8-a1dd-a5b56bad93b9'	System	24 Dec 2020 15:11:23
User entered 'No (N)'	System	24 Dec 2020 15:11:23

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-12-24T12:11:15', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'e783e9a3-a2ae-48f8-a1dd-a5b56bad93b9'	System	24 Dec 2020 15:11:23
User entered 'No (N)'	System	24 Dec 2020 15:11:23

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-12-24T12:11:19', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'e783e9a3-a2ae-48f8-a1dd-a5b56bad93b9'	System	24 Dec 2020 15:11:23
User entered '24 Dec 2020 12:11:19'	System	24 Dec 2020 15:11:23

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-12-31T07:06:41', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'dd242c54-d026-4ca3-8f21-e996e29c46f9'	System	31 Dec 2020 10:06:56
User entered 'No (N)'	System	31 Dec 2020 10:06:56

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-12-31T07:06:49', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'dd242c54-d026-4ca3-8f21-e996e29c46f9'	System	31 Dec 2020 10:06:56
User entered 'No (N)'	System	31 Dec 2020 10:06:56

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-12-31T07:06:53', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'dd242c54-d026-4ca3-8f21-e996e29c46f9'	System	31 Dec 2020 10:06:56
User entered '31 Dec 2020 07:06:53'	System	31 Dec 2020 10:06:56

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-01-07T06:59:02', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '6e50fbe9-a28d-4385-9ec1-b7a30af3fa3a'	System	07 Jan 2021 11:59:12
User entered 'No (N)'	System	07 Jan 2021 11:59:12

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-01-07T06:59:06', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '6e50fbe9-a28d-4385-9ec1-b7a30af3fa3a'	System	07 Jan 2021 11:59:12
User entered 'No (N)'	System	07 Jan 2021 11:59:12

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-01-07T06:59:09', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '6e50fbe9-a28d-4385-9ec1-b7a30af3fa3a'	System	07 Jan 2021 11:59:12
User entered '07 Jan 2021 06:59:09'	System	07 Jan 2021 11:59:12

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-01-15T09:44:38', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ffb8a3c9-6a08-42db-b3ed-2c7974dfbd74'	System	15 Jan 2021 14:44:46
User entered 'No (N)'	System	15 Jan 2021 14:44:46

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-01-15T09:44:41', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ffb8a3c9-6a08-42db-b3ed-2c7974dfbd74'	System	15 Jan 2021 14:44:46
User entered 'No (N)'	System	15 Jan 2021 14:44:46

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-01-15T09:44:43', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ffb8a3c9-6a08-42db-b3ed-2c7974dfbd74'	System	15 Jan 2021 14:44:46
User entered '15 Jan 2021 09:44:43'	System	15 Jan 2021 14:44:46

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-01-24T18:13:09', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f804b70b-5c42-46fe-b7f3-edabe351ba03'	System	24 Jan 2021 23:13:19
User entered 'No (N)'	System	24 Jan 2021 23:13:19

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-01-24T18:13:12', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f804b70b-5c42-46fe-b7f3-edabe351ba03'	System	24 Jan 2021 23:13:19
User entered 'No (N)'	System	24 Jan 2021 23:13:19

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-01-24T18:13:15', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f804b70b-5c42-46fe-b7f3-edabe351ba03'	System	24 Jan 2021 23:13:19
User entered '24 Jan 2021 18:13:15'	System	24 Jan 2021 23:13:19

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-01-30T12:00:36', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '47ddd8a5-c28a-40e5-aa22-a3f5bb438200'	System	30 Jan 2021 17:02:18
User entered 'No (N)'	System	30 Jan 2021 17:02:18

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-01-30T12:00:42', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '47ddd8a5-c28a-40e5-aa22-a3f5bb438200'	System	30 Jan 2021 17:02:18
User entered 'No (N)'	System	30 Jan 2021 17:02:18

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-01-30T12:00:45', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '47ddd8a5-c28a-40e5-aa22-a3f5bb438200'	System	30 Jan 2021 17:02:18
User entered '30 Jan 2021 12:00:45'	System	30 Jan 2021 17:02:18

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-02-06T12:01:17', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '9e02d999-6633-42ad-82dc-a26b97a831d5'	System	06 Feb 2021 17:04:43
User entered 'No (N)'	System	06 Feb 2021 17:04:43

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-02-06T12:01:20', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '9e02d999-6633-42ad-82dc-a26b97a831d5'	System	06 Feb 2021 17:04:43
User entered 'No (N)'	System	06 Feb 2021 17:04:43

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-02-06T12:01:24', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '9e02d999-6633-42ad-82dc-a26b97a831d5'	System	06 Feb 2021 17:04:43
User entered '06 Feb 2021 12:01:24'	System	06 Feb 2021 17:04:43

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-02-13T18:56:29', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4efdb41b-f2dc-445b-99c8-790dcc361104'	System	13 Feb 2021 23:56:50
User entered 'No (N)'	System	13 Feb 2021 23:56:50

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-02-13T18:56:32', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4efdb41b-f2dc-445b-99c8-790dcc361104'	System	13 Feb 2021 23:56:50
User entered 'No (N)'	System	13 Feb 2021 23:56:50

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-02-13T18:56:35', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4efdb41b-f2dc-445b-99c8-790dcc361104'	System	13 Feb 2021 23:56:50
User entered '13 Feb 2021 18:56:35'	System	13 Feb 2021 23:56:50

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-02-18T08:31:41', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1102138e-b499-4fbd-8026-0e5a73843f09'	System	18 Feb 2021 13:31:52
User entered 'No (N)'	System	18 Feb 2021 13:31:52

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-02-18T08:31:45', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1102138e-b499-4fbd-8026-0e5a73843f09'	System	18 Feb 2021 13:31:52
User entered 'No (N)'	System	18 Feb 2021 13:31:52

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-02-18T08:31:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1102138e-b499-4fbd-8026-0e5a73843f09'	System	18 Feb 2021 13:31:52
User entered '18 Feb 2021 08:31:47'	System	18 Feb 2021 13:31:52

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-02-27T12:00:26-05:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a46e96a4-bc74-4622-81ff-5a99865b10bf'	System	27 Feb 2021 17:00:50
User entered 'No (N)'	System	27 Feb 2021 17:00:50

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-02-27T12:00:29-05:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a46e96a4-bc74-4622-81ff-5a99865b10bf'	System	27 Feb 2021 17:00:50
User entered 'No (N)'	System	27 Feb 2021 17:00:50

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-02-27T12:00:32-05:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a46e96a4-bc74-4622-81ff-5a99865b10bf'	System	27 Feb 2021 17:00:50
User entered '27 Feb 2021 17:00:32'	System	27 Feb 2021 17:00:50

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-03-06T12:00:38-05:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8726135a-a96c-495c-8a2a-9d8b94b6c119'	System	06 Mar 2021 17:02:14
User entered 'No (N)'	System	06 Mar 2021 17:02:14

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-03-06T12:00:40-05:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8726135a-a96c-495c-8a2a-9d8b94b6c119'	System	06 Mar 2021 17:02:14
User entered 'No (N)'	System	06 Mar 2021 17:02:14

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-03-06T12:00:43-05:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8726135a-a96c-495c-8a2a-9d8b94b6c119'	System	06 Mar 2021 17:02:14
User entered '06 Mar 2021 12:00:43'	System	06 Mar 2021 17:02:14

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 21:35:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-03-12T09:19:52-05:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'c5898d6d-7537-43f3-a8f3-6658375097d1'	System	12 Mar 2021 14:20:04
User entered 'No (N)'	System	12 Mar 2021 14:20:04

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-03-12T09:19:55-05:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'c5898d6d-7537-43f3-a8f3-6658375097d1'	System	12 Mar 2021 14:20:04
User entered 'No (N)'	System	12 Mar 2021 14:20:04

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-03-12T09:19:57-05:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'c5898d6d-7537-43f3-a8f3-6658375097d1'	System	12 Mar 2021 14:20:04
User entered '12 Mar 2021 09:19:57'	System	12 Mar 2021 14:20:04

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 21:35:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-03-22T09:39:34-04:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ef5f9981-19b8-4533-8364-e75aa3184bc1'	System	22 Mar 2021 13:39:46
User entered 'No (N)'	System	22 Mar 2021 13:39:46

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-03-22T09:39:37-04:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ef5f9981-19b8-4533-8364-e75aa3184bc1'	System	22 Mar 2021 13:39:46
User entered 'No (N)'	System	22 Mar 2021 13:39:46

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-03-22T09:39:39-04:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ef5f9981-19b8-4533-8364-e75aa3184bc1'	System	22 Mar 2021 13:39:46
User entered '22 Mar 2021 09:39:39'	System	22 Mar 2021 13:39:46

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-03-29T15:34:30-03:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '41ce4c59-6d6b-4e44-a393-4096b4e9f568'	System	29 Mar 2021 18:34:38
User entered 'No (N)'	System	29 Mar 2021 18:34:38

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-03-29T15:34:32-03:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '41ce4c59-6d6b-4e44-a393-4096b4e9f568'	System	29 Mar 2021 18:34:38
User entered 'No (N)'	System	29 Mar 2021 18:34:38

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-03-29T15:34:34-03:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '41ce4c59-6d6b-4e44-a393-4096b4e9f568'	System	29 Mar 2021 18:34:38
User entered '29 Mar 2021 15:34:34'	System	29 Mar 2021 18:34:38

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-04-08T07:34:59-04:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '186dd34c-5d1c-4e38-ae9a-6233039d81f3'	System	08 Apr 2021 11:35:09
User entered 'No (N)'	System	08 Apr 2021 11:35:09

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-04-08T07:35:04-04:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '186dd34c-5d1c-4e38-ae9a-6233039d81f3'	System	08 Apr 2021 11:35:09
User entered 'No (N)'	System	08 Apr 2021 11:35:09

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-04-08T07:35:07-04:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '186dd34c-5d1c-4e38-ae9a-6233039d81f3'	System	08 Apr 2021 11:35:09
User entered '08 Apr 2021 07:35:07'	System	08 Apr 2021 11:35:09

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-04-18T17:59:19-04:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'aa1374dd-37f6-484c-a42c-cea06bf1f65a'	System	18 Apr 2021 21:59:29
User entered 'No (N)'	System	18 Apr 2021 21:59:29

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-04-18T17:59:21-04:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'aa1374dd-37f6-484c-a42c-cea06bf1f65a'	System	18 Apr 2021 21:59:29
User entered 'No (N)'	System	18 Apr 2021 21:59:29

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-04-18T17:59:25-04:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'aa1374dd-37f6-484c-a42c-cea06bf1f65a'	System	18 Apr 2021 21:59:29
User entered '18 Apr 2021 17:59:25'	System	18 Apr 2021 21:59:29

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-04-24T12:17:41-04:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'eb5d0efc-d4cc-4915-81a0-1af1e9774ea2'	System	24 Apr 2021 16:17:51
User entered 'No (N)'	System	24 Apr 2021 16:17:51

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-04-24T12:17:45-04:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'eb5d0efc-d4cc-4915-81a0-1af1e9774ea2'	System	24 Apr 2021 16:17:51
User entered 'No (N)'	System	24 Apr 2021 16:17:51

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-04-24T12:17:47-04:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'eb5d0efc-d4cc-4915-81a0-1af1e9774ea2'	System	24 Apr 2021 16:17:51
User entered '24 Apr 2021 12:17:47'	System	24 Apr 2021 16:17:51

FDA-CBER-2022-1614-0965943

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-05-03T12:44:04-04:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'fbc54175-4aff-4760-9367-ed2f03a0eb10'	System	03 May 2021 16:44:15
User entered 'No (N)'	System	03 May 2021 16:44:15

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Have you been exposed to someone with 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 (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-05-03T12:44:08-04:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'fbc54175-4aff-4760-9367-ed2f03a0eb10'	System	03 May 2021 16:44:15
User entered 'No (N)'	System	03 May 2021 16:44:15

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-05-03T12:44:11-04:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'fbc54175-4aff-4760-9367-ed2f03a0eb10'	System	03 May 2021 16:44:15
User entered '03 May 2021 12:44:11'	System	03 May 2021 16:44:15

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 21:35:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:35:53

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 21:35:53

FDA-CBER-2022-1614-0966001

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:35:53

FDA-CBER-2022-1614-0966033

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 21:35:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 21:35:53

FDA-CBER-2022-1614-0966113

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:35:53

FDA-CBER-2022-1614-0966117

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 21:35:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 21:35:53

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:35:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 21:35:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 21:35:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:13:10
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:10

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:13:10

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:38:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-03-06T12:00:51-05:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '40b3b631-e715-4906-a526-926c6f5ff75a'	System	06 Mar 2021 17:03:12
User entered 'No (N)'	System	06 Mar 2021 17:03:12

US3352299

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:13:10

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:38:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2021-03-06T12:00:54-05:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '40b3b631-e715-4906-a526-926c6f5ff75a'	System	06 Mar 2021 17:03:12
User entered '06 Mar 2021 12:00:54'	System	06 Mar 2021 17:03:12

US3352299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:40:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:26:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 17:22:45

US3352299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:40:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:26:08
User entered '23 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 17:22:45

US3352299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:40:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:26:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Nov 2020 17:22:45

US3352299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:40:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:26:08
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 17:22:45

US3352299

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:40:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:27:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 17:22:48

US3352299

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:40:11
User entered '1'	System	25 Nov 2020 17:22:48

US3352299
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:13:10

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:31:54
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	29 Dec 2020 19:25:30

US3352299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:31:54
User entered '29 Dec 2020'	Sara Gomez (b) (4) (b) (4)	29 Dec 2020 19:25:30

US3352299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:31:54
User entered 'Contact Made (CONTACT MADE)'	Sara Gomez (b) (4) (b) (4)	29 Dec 2020 19:25:30

US3352299
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:13:10
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:31:54
User entered empty.	Sara Gomez (b) (4) (b) (4)	29 Dec 2020 19:25:30

US3352299

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:31:57
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	27 Jan 2021 12:57:17

US3352299
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:13:10
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User entered '1'	System	27 Jan 2021 12:57:17

US3352299

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:32:28
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	27 Jan 2021 12:57:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:52:34
User closed query 'Source states 26Jan2021. Please review and reconcile. ' (Site from CRA).		16 Apr 2021 18:52:32
Query 'Source states 26Jan2021. Please review and reconcile. ' answered with 'DATA IS CORRECT. SAFETY CALL WAS PERFORMED 27/JAN/2021 AND OPEN LABEL DAY 1 WAS PERFORMED 26/JAN/2021' (Site from CRA).		14 Apr 2021 20:38:58
User opened query 'Source states 26Jan2021. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:32:48
DataPoint Un-verified.		12 Apr 2021 17:32:31
DataPoint Verified.		12 Apr 2021 17:32:28
User entered '27 Jan 2021'	Yulexis Amestoy (b) (4) (b) (4)	27 Jan 2021 12:57:26

US3352299

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:32:28
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4) (b) (4)	27 Jan 2021 12:57:26

US3352299
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:13:10
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:32:28
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	27 Jan 2021 12:57:26

US3352299
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:32:52
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	27 Jan 2021 12:57:30

US3352299
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:13:10
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User entered '1'	System	27 Jan 2021 12:57:30

US3352299

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:33:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:51:29

US3352299
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:33:31
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 18:51:29

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:33:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Feb 2021 18:51:29

US3352299

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:33:31
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:51:29

US3352299

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:33:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:51:22

US3352299

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:46
User entered '1'	System	23 Feb 2021 18:51:22

US3352299
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:13:10
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:07
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	22 Mar 2021 15:03:12

US3352299
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:13:10
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:07
User entered '22 Mar 2021'	Matthew Muniz (b) (4)	22 Mar 2021 15:03:12

US3352299
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:13:10

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 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:07
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	22 Mar 2021 15:03:12

US3352299
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:13:10
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User entered 'VISIT4'	System	22 Mar 2021 15:03:12

US3352299
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:28
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 23:11:27

US3352299
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:28
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 23:11:27

US3352299
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:28
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 23:11:27

US3352299
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User entered empty.	System	30 Mar 2021 23:11:27

US3352299
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:28
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 23:11:27

US3352299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:28
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 23:11:27

US3352299
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:28
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 23:11:27

US3352299
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:28
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 23:11:27

US3352299
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User entered empty.	System	30 Mar 2021 23:11:27

US3352299
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:28
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 23:11:27

FDA-CBER-2022-1614-0966228

US3352299
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User entered empty.	System	30 Mar 2021 23:11:27

US3352299
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:28
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 23:11:27

US3352299
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User entered empty.	System	30 Mar 2021 23:11:27

US3352299
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:28
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 23:11:27

US3352299
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User entered empty.	System	30 Mar 2021 23:11:27

US3352299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:10

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12

US3352299
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:13:10
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12

US3352299

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:10

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:39
User entered 'No (N)'	Matthew Muniz (b) (4)	22 Mar 2021 15:03:34

US3352299

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:10

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:39
User entered empty.	Matthew Muniz (b) (4)	22 Mar 2021 15:03:34

US3352299

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:10

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:48
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	22 Mar 2021 15:04:40

US3352299

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:10

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:48
User entered '22 Mar 2021'	Matthew Muniz (b) (4)	22 Mar 2021 15:04:40

US3352299

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:48
User entered '09:59'	Matthew Muniz (b) (4)	22 Mar 2021 15:04:40

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User entered '22 Mar 2021 09:59'	System	22 Mar 2021 15:04:40

US3352299
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:28:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:53
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	22 Mar 2021 15:04:51

US3352299
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:13:10
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User entered '1'	System	22 Mar 2021 15:04:51

Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Apr 2021 18:05:22

US3352299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User entered '26 Apr 2021'	(b) (4), (b) (6)	26 Apr 2021 18:05:22

US3352299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Apr 2021 18:05:22

US3352299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:10

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 18:05:22

US3352299

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Apr 2021 18:05:26

US3352299

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:10

Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 18:05:26

US3352299

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

Form: Visit Date

Generated On: 09 Jun 2021 17:13:10

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:16
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Jan 2021 15:14:14

US3352299

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

Form: Visit Date

Generated On: 09 Jun 2021 17:13:10

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:16
User entered '26 Jan 2021'	Matthew Muniz (b) (4)	26 Jan 2021 15:14:14

US3352299

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

Form: Visit Date

Generated On: 09 Jun 2021 17:13:10

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 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:16
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	26 Jan 2021 15:14:14

US3352299

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

Form: Visit Date

Generated On: 09 Jun 2021 17:13:10

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 15:14:14

US3352299

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:10

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:52
User entered '26 Jan 2021'	Matthew Muniz (b) (4)	26 Jan 2021 15:16:06

US3352299

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:52
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	08 Apr 2021 15:51:07
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:10:43

US3352299

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:10

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:52
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Jan 2021 15:16:06

US3352299

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:10

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:52
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 21:16:49
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Data updated.' (Site from DM).	Rosaidaliz Carreira (b) (4) (b) (4)	08 Apr 2021 15:51:36
User entered 'Amendment 6 or later (Amendment 6 or later)'	Rosaidaliz Carreira (b) (4) (b) (4)	08 Apr 2021 15:51:07
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 14:28:12
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:10:43

US3352299

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:10

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:52
User entered '26 Jan 2021'	Matthew Muniz (b) (4)	26 Jan 2021 15:16:06

US3352299

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:10

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:52
User entered 'mRNA-1273 (mRNA-1273)'	Matthew Muniz (b) (4)	26 Jan 2021 15:16:06

US3352299

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:10

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:52
User entered 'mRNA-1273 (mRNA-1273)'	Matthew Muniz (b) (4)	26 Jan 2021 15:16:06

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3352299

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:10

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:52
User entered 'mRNA-1273 (mRNA-1273)'	Matthew Muniz (b) (4)	26 Jan 2021 15:16:06

US3352299

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:10

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:52
User entered 'No (N)'	Matthew Muniz (b) (4)	26 Jan 2021 15:16:06

US3352299

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:10

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User entered empty.	System	26 Jan 2021 15:16:06

US3352299

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:10

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User entered empty.	System	26 Jan 2021 15:16:06

US3352299

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:10

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:02:01
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Jan 2021 15:16:16

US3352299

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:10

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:02:01
User entered '26 Jan 2021'	Matthew Muniz (b) (4)	26 Jan 2021 15:16:16

US3352299

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:02:01
User entered '09:43'	Matthew Muniz (b) (4)	26 Jan 2021 15:16:16

US3352299

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:10

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:12
User entered '26 Jan 2021 09:43'	System	26 Jan 2021 15:16:16

US3352299

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:13:10

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:07
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:02:06
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Jan 2021 15:16:25

US3352299

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:13:10

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:07
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:02:06
User entered '26 Jan 2021'	Matthew Muniz (b) (4)	26 Jan 2021 15:16:25

US3352299

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:07
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:02:06
User entered '09:35'	Matthew Muniz (b) (4)	26 Jan 2021 15:16:25

US3352299

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:13:10

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:51:07
User entered '26 Jan 2021 09:35'	System	26 Jan 2021 15:16:25

US3352299

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:13:10

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:01:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:20:28

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

AEID

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 15:30:30
Un-reviewed for Safety.		19 Feb 2021 15:30:25
Reviewed for Safety.		19 Feb 2021 15:29:40
Un-reviewed for Safety.		19 Feb 2021 15:29:37
DataPoint Verified.		02 Dec 2020 19:20:11
Reviewed for Safety.		13 Nov 2020 13:23:18
User entered 'USA-US066-2020-mRNA-1273-P301000005'	System	13 Nov 2020 13:23:15
User entered 'New'	(b) (4), (b) (6)	13 Nov 2020 13:23:15

US3352299
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:13:10
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:26:03
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash vesicular, LLT: Vesicular rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 12:28:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 12:28:05
User closed query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 05:21:11
Query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'As per Sub I AND MEDICAL RECORDS thi is the best terminolgy.' (Site from DM).	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 19:38:50
Data point term sent to Coder	System	18 Feb 2021 19:38:21
DataPoint Un-verified.	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 19:37:47
Coding entries removed.	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 19:37:47
User entered 'DISSEMINATED VESICULAR REACTION' reason for change: New Information	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 19:37:47
User opened query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:22:59
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:52:37
User closed query 'PV Query: Please clarify no definitive unifying diagnosis was identified for the 3 events reported. ' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 19:06:01

US3352299
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:13:10
Adverse event

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide alternative reasoning for events disseminated vesicular rash, elevated transaminase level, and rash skin eruption, when known. If unknown please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 19:05:58
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash vesicular, LLT: Vesicular rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 12:42:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 12:42:54
Query 'PV Query: Please clarify no definitive unifying diagnosis was identified for the 3 events reported. ' answered with 'updated' (Site from Safety).	Matthew Muniz (b) (4)	08 Dec 2020 19:32:30
Data point term sent to Coder	System	08 Dec 2020 19:30:41
Query 'PV Query: Please provide alternative reasoning for events disseminated vesicular rash, elevated transaminase level, and rash skin eruption, when known. If unknown please state so.' answered with 'updated' (Site from Safety).	Matthew Muniz (b) (4)	08 Dec 2020 19:30:33
DataPoint Un-verified.	Matthew Muniz (b) (4)	08 Dec 2020 19:30:12
Coding entries removed.	Matthew Muniz (b) (4)	08 Dec 2020 19:30:12
User entered 'DISSEMINATED VESICULAR RASh' reason for change: New Information	Matthew Muniz (b) (4)	08 Dec 2020 19:30:12
User opened query 'PV Query: Please clarify no definitive unifying diagnosis was identified for the 3 events reported. ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:39:50
User opened query 'PV Query: Please provide alternative reasoning for events disseminated vesicular rash, elevated transaminase level, and rash skin eruption, when known. If unknown please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:22:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:13
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event if biopsy or other testing/exam provides a definitive diagnosis.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 17:23:22

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash vesicular, LLT: Vesicular rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:10:59
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 20:10:59
Data point term sent to Coder	System	24 Nov 2020 18:40:45
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event if biopsy or other testing/exam provides a definitive diagnosis.' answered with 'AE TERM HAS BEEN UPDATED BASED OFF OF MEDICAL RECORDS.' (Site from Safety).	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:40:24
Coding entries removed.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:39:51
User entered 'DISSEMINATED VESICULAR RASH ALL OVER BODY' reason for change: New Information	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:39:51
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event if biopsy or other testing/exam provides a definitive diagnosis.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:44:06
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral skin infection, LLT: Viral skin infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 15:48:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 15:48:31
Data point term sent to Coder	System	12 Nov 2020 15:47:26
User entered 'VIRAL SKIN CONDITION'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:14
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:16
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:17
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

FDA-CBER-2022-1614-0966280

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:19
User entered '08 Nov 2020'	Rosaidaliz Carreira (b) (4)	12 Nov 2020 15:46:30

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:21
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

FDA-CBER-2022-1614-0966282

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 15:46:30

US3352299
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:22
User entered 'No (N)' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:39:51
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:24
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 17:23:19
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'DATE HAS BEEN UPDATED.' (Site from Safety).	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:40:41
User entered '13 Nov 2020' reason for change: New Information	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:39:51
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:43:07
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:27
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 15:46:30

US3352299
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:13:10
Severity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'Please clarify what 4 = in source. In AE Severity section in source the # 4 does not have an indication, please clarify in source. ' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 15:52:58
Query 'Please clarify what 4 = in source. In AE Severity section in source the # 4 does not have an indication, please clarify in source. ' answered with 'hospitalized added to source' (Site from CRA).	Matthew Muniz (b) (4)	08 Dec 2020 18:47:16
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:28
User opened query 'Please clarify what 4 = in source. In AE Severity section in source the # 4 does not have an indication, please clarify in source. ' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 19:03:52
User entered 'Grade 4 (Grade 4)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:13:10
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:30
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

FDA-CBER-2022-1614-0966289

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:32
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:35
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:13:10
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'PV Query: Hospital discharge summary was not received. Please resend the hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 14:44:27
Query 'PV Query: Hospital discharge summary was not received. Please resend the hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'it was sent alredy .' (Site from Safety).	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 19:39:59
User opened query 'PV Query: Hospital discharge summary was not received. Please resend the hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:49:18
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:34
User closed query 'Per CDM: Kindly update the hospital discharge date when data is available. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 07:12:09
Query 'Per CDM: Kindly update the hospital discharge date when data is available. Thank you.' answered with 'DATE HAS BEEN ENTERED.' (Site from DM).	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 16:08:45
User opened query 'Per CDM: Kindly update the hospital discharge date when data is available. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 10:21:46
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), (b) (6)	13 Nov 2020 10:20:40
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 with 'Data pending. Will be updated once site has further information from the subject.' (Site from System).	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:49:49

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
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	12 Nov 2020 15:46:30
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User closed query 'PV Query: For the event, disseminated vesicular reaction, hospital admission date was reported as 08 Nov 2020. Please confirm this date is correct or update to admission date of 11 Nov 2020 that was reported with the other two events.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 20:52:11
Query 'PV Query: For the event, disseminated vesicular reaction, hospital admission date was reported as 08 Nov 2020. Please confirm this date is correct or update to admission date of 11 Nov 2020 that was reported with the other two events.' answered with 'UPDATED' (Site from Safety).	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 14:48:35
DataPoint Un-verified.	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 14:48:27
User entered '11 Nov 2020' reason for change: Data Entry Error	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 14:48:27
User opened query 'PV Query: For the event, disseminated vesicular reaction, hospital admission date was reported as 08 Nov 2020. Please confirm this date is correct or update to admission date of 11 Nov 2020 that was reported with the other two events.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 13:18:16
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:37
User entered '08 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 14:28:03
Query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' answered with 'Medical records were emailed on 24NOV2020 to the email listed above.' (Site from Safety).	Rosaidaliz Carreira (b) (4) (b) (4)	10 Dec 2020 17:50:10
User opened query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:08:35
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:39
User entered '13 Nov 2020' reason for change: New Information	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 16:08:31
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:13:10
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:41
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:45
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:47
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:49
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:51
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

FDA-CBER-2022-1614-0966300

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:52
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:13:10
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:54
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:56
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 17:23:16
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' answered with 'DATA UPDATED AS PER QUERY REQUEST.' (Site from Safety).	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:41:00
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:39:51
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:42:49
User entered 'None (NONE)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:13:10
None

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:59:08
DataPoint Un-verified.	Matthew Muniz (b) (4)	08 Dec 2020 19:32:12
User entered '0' reason for change: Data Entry Error	Matthew Muniz (b) (4)	08 Dec 2020 19:32:12
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:20:59
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:57:42
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:11:50
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 19:57:39
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 19:57:26
User entered '0' reason for change: Data Entry Error		01 Apr 2021 19:57:26
DataPoint Verified.		31 Mar 2021 15:48:03
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		24 Mar 2021 06:38:08
User entered '1' reason for change: Data Entry Error	Wanda Delgado (b) (4)	05 Mar 2021 17:41:39
DataPoint Un-verified.	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 19:46:00
User entered '0' reason for change: Data Entry Error	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 19:46:00
User closed query 'Please verify per source Con Med List this SAE has Con Meds. ' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 15:59:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:59:06

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Concomitant Medication

Audit	User	Time (GMT)
Query 'Please verify per source Con Med List this SAE has Con Meds. ' answered with 'updated' (Site from CRA).	Matthew Muniz (b) (4)	08 Dec 2020 19:32:32
DataPoint Un-verified.	Matthew Muniz (b) (4)	08 Dec 2020 19:32:12
User entered '1' reason for change: Data Entry Error	Matthew Muniz (b) (4)	08 Dec 2020 19:32:12
User opened query 'Please verify per source Con Med List this SAE has Con Meds. ' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:02:49
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:21:00
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'Per DM CLR - RQ: Response noted. However, please tick this field if therapeutic surgery/procedure is given. Either update this field or update Con Proc eCRF to include a therapeutic procedure.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 06:26:56
Query 'Per DM CLR - RQ: Response noted. However, please tick this field if therapeutic surgery/procedure is given. Either update this field or update Con Proc eCRF to include a therapeutic procedure.' answered with 'Subject had a Punch Biopsy, a skin Biopsy of right arm, and a general skin Biopsy associated with this SAE. Please note these can be considered as screening procedures. As per medical records, no therapeutic procedures were performed. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 20:02:44
User opened query 'Per DM CLR - RQ: Response noted. However, please tick this field if therapeutic surgery/procedure is given. Either update this field or update Con Proc eCRF to include a therapeutic procedure.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 06:38:36
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 05:32:32
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'See Con Procedures biopsis were performed.' (Site from DM).	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 19:45:49
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 06:14:03

FDA-CBER-2022-1614-0966307

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:53:25
User closed query 'Please clarify subject had procedures of push biopsy and skin biopsies during hospitalization.' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 15:53:22
Query 'Please clarify subject had procedures of push biopsy and skin biopsies during hospitalization.' answered with 'updated' (Site from CRA).	Matthew Muniz (b) (4)	08 Dec 2020 19:32:34
DataPoint Un-verified.	Matthew Muniz (b) (4)	08 Dec 2020 19:32:12
User entered '1' reason for change: Data Entry Error	Matthew Muniz (b) (4)	08 Dec 2020 19:32:12
User opened query 'Please clarify subject had procedures of push biopsy and skin biopsies during hospitalization.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:30:07
Query 'Please clarify subject had procedures of push biopsy, skin biopsies during hospitalization' canceled (Site from CRA).		02 Dec 2020 20:29:40
User opened query 'Please clarify subject had procedures of push biopsy, skin biopsies during hospitalization' (Site from CRA).		02 Dec 2020 20:29:28
Query 'Please clarify subject had procedures during hospitalization. ' canceled (Site from CRA).		02 Dec 2020 20:28:47
User opened query 'Please clarify subject had procedures during hospitalization. ' (Site from CRA).		02 Dec 2020 20:28:25
DataPoint Verified.		02 Dec 2020 19:21:02
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:13:10
Outcome

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:21:04
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 17:23:14
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'DATA UPDATED.' (Site from Safety).	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:41:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:39:51
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:43:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:21:05
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

FDA-CBER-2022-1614-0966310

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'PV Query: Please provide any workups for elevated liver transaminase level: hepatitis viruses, other viral infections, alcoholic liver dysfunction, autoimmune diseases, and imaging diagnosis.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 15:25:31
User closed query 'PV Query: Please provide a note of dermatological consult.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 15:25:26
User closed query 'PV Query: Please provide the results of the skin biopsy.' (Site from Safety).		19 Feb 2021 15:25:23
User closed query 'PV Query: Please clarify no definitive unifying diagnosis was identified for the 3 events reported.' (Site from Safety).		19 Feb 2021 15:25:18
User closed query 'PV Query: Please provide alternative reasoning for events disseminated vesicular rash, elevated transaminase level, and rash skin eruption, when known. If unknown please state so.' (Site from Safety).		19 Feb 2021 15:25:14
Query 'PV Query: Please provide alternative reasoning for events disseminated vesicular rash, elevated transaminase level, and rash skin eruption, when known. If unknown please state so.' answered with 'please refer to medical records,forthermore conctat the Principal Investdator aboit details of the event.' (Site from Safety).	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 20:31:35
Query 'PV Query: Please provide any workups for elevated liver transaminase level: hepatitis viruses, other viral infections, alcoholic liver dysfunction, autoimmune diseases, and imaging diagnosis.' answered with 'Significant Lab results ALT of 138 uil billirubin direct 0.4 mg ldl, CRP of 122.0 mg. AST 102 ul SARS -COV-2 IgG negative .' (Site from Safety).	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 20:26:20
Query 'PV Query: Please provide a note of dermatological consult.' answered with 'Assessment plan consultation: Rash/Skin eruption. Differencial diagnosis : bullous disease vs erythema multiforme vs bullons disease vs vaccine hypersensitivity.' (Site from Safety).	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 20:14:28

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of the skin biopsy.' answered with 'negative IgG ,IgA, IgM, negative for clinically relevant deposition. Subepidermal vesicle formation with focal epidermal necrosis, necrotic keratinocytes,and an underlying dense superficial lymphoesosinophilic infiltrate. ' (Site from Safety).	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 20:04:52
Query 'PV Query: Please clarify no definitive unifying diagnosis was identified for the 3 events reported.' answered with 'Confirmed no definitive unifying diagnosis.' (Site from Safety).	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 19:55:11
User opened query 'PV Query: Please provide any workups for elevated liver transaminase level: hepatitis viruses, other viral infections, alcoholic liver dysfunction, autoimmune diseases, and imaging diagnosis.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:52:02
User opened query 'PV Query: Please provide a note of dermatological consult.' (Site from Safety).		16 Dec 2020 18:50:01
User opened query 'PV Query: Please provide the results of the skin biopsy.' (Site from Safety).		16 Dec 2020 18:49:33
User opened query 'PV Query: Please clarify no definitive unifying diagnosis was identified for the 3 events reported.' (Site from Safety).		16 Dec 2020 18:48:30
User opened query 'PV Query: Please provide alternative reasoning for events disseminated vesicular rash, elevated transaminase level, and rash skin eruption, when known. If unknown please state so.' (Site from Safety).		16 Dec 2020 18:48:13
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:21:07
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) (6)	25 Nov 2020 17:23:12
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test, with biopsy results, used to diagnose or monitor the viral disease. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 17:23:10

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 17:23:08
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'MEDICATIONS HAVE BEEN ADDED TO COM MEDICATION FORM.' (Site from Safety).	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:37:19
Query 'PV Query: Please provide any relevant laboratory and diagnostic test, with biopsy results, used to diagnose or monitor the viral disease. Please include units and reference ranges if applicable.' answered with 'SIGNIFICANT LAB RESULTS CONSIST OF ALT OF 138 U/L. BILIRUBIN DIRECT 0.4 MG/DL. CRP OF 122.0 MG/L. AST 102 U/L. SARS-COV-2 IgG NEGATIVE. SKIN BIOPSY, SKIN INTERPRETATION: NEGATIVE DIRECT IMMUNOFLUORESCENCE STUDY. IgG: NEGATIVE FOR CLINICALLY RELEVANT DEPOSITION. IgA: NEGATIVE FOR CLINICALLY RELEVANT DEPOSITION. IgM: NEGATIVE FOR CLINICALLY RELEVANT DEPOSITION. C3: NEGATIVE FOR CLINICALLY RELEVANT DEPOSITION. FIBRINOGEN: NEGATIVE FOR CLINICALLY RELEVANT DEPOSITION. PUNCH BIOPSY DIRECT IMMUNOFLOURESENCE STUDIES ARE NEGATIVE FOR ANTIBODY DEPOSITION.' (Site from Safety).	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:32:45

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Narrative

Audit	User	Time (GMT)
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 'SARS-CoV-2 TEST DONE ON 11NOV2020 WITH A NEGATIVE RESULT.' (Site from Safety).	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:39:28
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:43:40
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test, with biopsy results, used to diagnose or monitor the viral disease. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:43:16
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)	20 Nov 2020 19:42:56
User entered 'Subject started with blisters all over his body more prominent to his mouth. He went to family doctor yesterday and was recommended to go to the hospital in view of his clinical presentation. Subject's wife reported he was admitted in the hospital yesterday 11NOV2020 at 1030 am. Had a skin biopsy done in which results are pending. She mentioned he was given a steriod antiviral and pain medications. Pending medical records.'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:10

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

AEID

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 15:30:30
Un-reviewed for Safety.		19 Feb 2021 15:30:25
Reviewed for Safety.		19 Feb 2021 15:29:40
Un-reviewed for Safety.		19 Feb 2021 15:29:37
DataPoint Verified.		02 Dec 2020 19:43:32
Reviewed for Safety.		25 Nov 2020 17:23:53
User entered 'USA-US066-2020-mRNA-1273-P301000005'		25 Nov 2020 17:23:40

US3352299
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:13:10
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 07:19:47
Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' answered with 'associated with disemminated vesicular reaction. Ae term correct as entered. ' (Site from DM).	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 14:53:31
User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 08:13:01
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:53:33
User coded data point as SOC: Investigations, HLGT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Hepatic enzyme increased, LLT: Elevated liver enzymes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 12:42:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 12:42:52
Data point term sent to Coder	System	08 Dec 2020 19:37:57
DataPoint Un-verified.	Matthew Muniz (b) (4)	08 Dec 2020 19:37:01
Coding entries removed.	Matthew Muniz (b) (4)	08 Dec 2020 19:37:01
User entered 'ELEVATED liver TRANSAMINASE LEVEL' reason for change: Data Entry Error	Matthew Muniz (b) (4)	08 Dec 2020 19:37:01
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:43:34

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Transaminases increased, LLT: Transaminases increased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:09:58
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 19:09:58
Data point term sent to Coder	System	24 Nov 2020 18:46:00
User entered 'ELEVATED TRANSAMINASE LEVEL'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:43:37
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:13:10
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:43:46
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:43:49
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:43:58
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:00
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:01
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:03
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:06
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Severity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:24:21
DataPoint Un-verified.	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 20:55:47
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Per Query Resolution	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 20:55:47
User closed query 'Please clarify what 4 = in source. In AE Severity section in source the # 4 does not have an indication, please clarify in source.' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 15:55:02
Query 'Please clarify what 4 = in source. In AE Severity section in source the # 4 does not have an indication, please clarify in source.' answered with 'updated' (Site from CRA).	Matthew Muniz (b) (4)	08 Dec 2020 19:35:50
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:08
User opened query 'Please clarify what 4 = in source. In AE Severity section in source the # 4 does not have an indication, please clarify in source.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 19:22:04
User entered 'Grade 4 (Grade 4)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:13:10
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:10
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:12
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:14
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:15
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:17
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:21
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:23
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

FDA-CBER-2022-1614-0966338

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:24
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:26
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:27
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:29
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:33
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:13:10
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:35
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:36
User entered 'Not Applicable (NOT APPLICABLE)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

None

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'PER DM CLR Requery-Response noted,as confirmed no treatment given, severity will be updated to 3 .,however, still Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 05:30:30
Query 'PER DM CLR Requery-Response noted,as confirmed no treatment given, severity will be updated to 3 .,however, still Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given.' answered with 'No treament given for this condition, refer to medical records from the hospitalization. ' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 18:05:01
User opened query 'PER DM CLR Requery-Response noted,as confirmed no treatment given, severity will be updated to 3 .,however, still Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 05:27:25
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 05:27:25

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

None

Audit	User	Time (GMT)
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'confirmed no treatment given, severity will be updated to 3 .' (Site from DM).	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 20:55:29
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:23:18
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:40
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:43
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:44
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:44:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:45:00
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'PV Query: Please provide date AST, ALT and bilirubin testing was performed with reference ranges. If reference ranges unknown, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 14:28:27
User closed query 'PV Query: Please provide additional testing results for AST and ALT and bilirubin, with date(s) performed, reference ranges and units.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 14:28:22
Query 'PV Query: Please provide date AST, ALT and bilirubin testing was performed with reference ranges. If reference ranges unknown, please state so.' answered with 'Previously response' (Site from Safety).	Rosaidaliz Carreira (b) (4) (b) (4)	10 Dec 2020 19:38:10
Query 'PV Query: Please provide additional testing results for AST and ALT and bilirubin, with date(s) performed, reference ranges and units.' answered with 'ALT of 138 U/L on 11NOV2020 with reference ranges of for males 16-65 on 12NOV2020 value was at 87 U/L with same reference range. AST on 11/11/2020 was 102 U/L with reference range 8-37. AST on 11/12/2020 36 U/L with reference ranges 8-37. Total bilirubin on 11/11/20 2.3 mg/dL with reference range 0.2-2.0. on 11/12/2020 1.5 mg/dL with reference range of 0.2-2.2.' (Site from Safety).	Rosaidaliz Carreira (b) (4) (b) (4)	10 Dec 2020 19:37:29
User opened query 'PV Query: Please provide date AST, ALT and bilirubin testing was performed with reference ranges. If reference ranges unknown, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:07:17
User opened query 'PV Query: Please provide additional testing results for AST and ALT and bilirubin, with date(s) performed, reference ranges and units.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:06:48
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:45:07
User entered 'DATA OBTAINED FROM SUBJECTS MEDICAL RECORDS WHICH HAVE BEEN REDACTED AND SUBMITTED TO SAFETY.'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:10

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

AEID

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 15:30:30
Un-reviewed for Safety.		19 Feb 2021 15:30:25
Reviewed for Safety.		19 Feb 2021 15:29:40
Un-reviewed for Safety.		19 Feb 2021 15:29:37
DataPoint Verified.		02 Dec 2020 19:55:12
Reviewed for Safety.		25 Nov 2020 17:24:23
User entered 'USA-US066-2020-mRNA-1273-P301000005'		25 Nov 2020 17:24:18

US3352299
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:13:10
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:47:52
User closed query 'Per DM CLR: Please review AE and please update to specify the type of Rash (e.g. Maculopapular, Pustular, etc.) and if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 07:20:58
Query 'Per DM CLR: Please review AE and please update to specify the type of Rash (e.g. Maculopapular, Pustular, etc.) and if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'CORRECTED AS ENTERED' (Site from DM).	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 14:35:19
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Generalized rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Mar 2021 20:58:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Mar 2021 20:58:50
User opened query 'Per DM CLR: Please review AE and please update to specify the type of Rash (e.g. Maculopapular, Pustular, etc.) and if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 08:13:38
User closed query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Right deltoid, etc) and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 05:28:40
Data point term sent to Coder	System	18 Feb 2021 20:59:26

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Adverse event

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Right deltoid, etc) and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'AE TERMONOLOGY WAS UPDATED' (Site from DM).	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 20:59:21
DataPoint Un-verified.	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 20:58:53
Coding entries removed.	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 20:58:53
User entered 'GENERALIZED RASH SKIN ERUPTION' reason for change: Data Entry Error	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 20:58:53
User opened query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Right deltoid, etc) and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:23:41
User closed query 'PC Query: PV Query: Please describe how the rash skin eruption differed from the disseminated vesicular rash warranting reporting as a separate event.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 14:32:40
Query 'PC Query: PV Query: Please describe how the rash skin eruption differed from the disseminated vesicular rash warranting reporting as a separate event.' answered with 'The disseminated vesicular rash was the admitted diagnosis and the rash skin eruption was diagnosos used for hosputal discharge. The other option can be to remove the rask skin eruption as an AE and reopen the disseminated vesicular rash with a different severity. ' (Site from Safety).	Rosaidaliz Carreira (b) (4) (b) (4)	10 Dec 2020 19:44:59
Query 'PV Query: Please clarify no definitive unifying diagnosis was identified for the 3 events reported. ' canceled (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:39:30
User opened query 'PV Query: Please clarify no definitive unifying diagnosis was identified for the 3 events reported. ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:38:56

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Adverse event

Audit	User	Time (GMT)
Query 'PV Query: Please provide alternative reasoning for events disseminated vesicular rash, elevated transaminase level, and rash skin eruption, when known. If unknown please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:18:40
User opened query 'PC Query: PV Query: Please describe how the rash skin eruption differed from the disseminated vesicular rash warranting reporting as a separate event.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:17:01
Query 'Please describe how the rash skin eruption differed from the disseminated vesicular rash warranting reporting as a separate event.' canceled (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:15:14
User opened query 'Please describe how the rash skin eruption differed from the disseminated vesicular rash warranting reporting as a separate event.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:01:29
User opened query 'PV Query: Please provide alternative reasoning for events disseminated vesicular rash, elevated transaminase level, and rash skin eruption, when known. If unknown please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 18:59:02
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:55:11
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Skin eruption - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:31:04
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 20:31:04
Data point term sent to Coder	System	24 Nov 2020 18:49:07
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:55:08
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:55:05
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:55:02
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:55:01
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:54:57
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:11:50
DataPoint Un-verified.		01 Apr 2021 20:08:01
User entered 'No (N)' reason for change: New Information		01 Apr 2021 20:08:01
DataPoint Verified.		02 Dec 2020 19:54:58
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:13:10
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:11:50
DataPoint Un-verified.		01 Apr 2021 20:08:01
User entered '15 Dec 2020' reason for change: Data Entry Error		01 Apr 2021 20:08:01
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		19 Feb 2021 15:26:09
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date will be provide ' (Site from Safety).	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 20:58:17
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 15:32:46
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:54:55
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:54:54
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

FDA-CBER-2022-1614-0966368

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

AE End Date and Time (derived)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date for generalized rash skin eruption (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:37:23
User opened query 'PV Query: Please provide the event end date for generalized rash skin eruption (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 13:19:06
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available for even #3, rash skin eruption.' canceled (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 15:32:28
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available for even #3, rash skin eruption.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:03:21
Query 'PV Query: Please provide the final event outcome, when available for even #3, rash skin eruption. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:02:44
User opened query 'PV Query: Please provide the final event outcome, when available for even #3, rash skin eruption. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 18:59:07
User entered empty.	System	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Severity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:54:53
User entered 'Grade 3/Severe (Grade 3/Severe)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:13:10
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:54:26
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:54:22
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:54:20
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:54:19
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:54:16
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'PV Query: Hospital discharge summary was not received. Please resend the hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 12:59:38
Query 'PV Query: Hospital discharge summary was not received. Please resend the hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'The discharge summary for the event was sent with the terminology "Admission Information Diagnosis: Rash/Skin Eruption most likely secondary to COVID vaccine VS HSV" The date of the discharge paper is 13NOV2020. The medical records will be resent today.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 20:06:22
User opened query 'PV Query: Hospital discharge summary was not received. Please resend the hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 13:19:44
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:54:14
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:13:10
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:54:13
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:13:10
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:54:10
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:54:07
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:54:09
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:54:05
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:54:03
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:13:10
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:54:01
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:54:00
User entered 'Not Applicable (NOT APPLICABLE)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

None

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:56:02
DataPoint Un-verified.	Rosaidaliz Carreira (b) (4) (b) (4)	10 Dec 2020 19:46:34
User entered '0' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4) (b) (4)	10 Dec 2020 19:46:34
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:53:57
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'Per source in Concomitant Medications Log this SAE has, Hydromorphone, Ondansetron, Prednisone, Sodium chloride, Triamcinolone, and Acetaminophen. ' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 15:56:14
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:56:12
Query 'Per source in Concomitant Medications Log this SAE has, Hydromorphone, Ondansetron, Prednisone, Sodium chloride, Triamcinolone, and Acetaminophen. ' answered with 'Data corrected.' (Site from CRA).	Rosaidaliz Carreira (b) (4) (b) (4)	10 Dec 2020 19:46:43
DataPoint Un-verified.	Rosaidaliz Carreira (b) (4) (b) (4)	10 Dec 2020 19:46:34
User entered '1' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4) (b) (4)	10 Dec 2020 19:46:34
User opened query 'Per source in Concomitant Medications Log this SAE has, Hydromorphone, Ondansetron, Prednisone, Sodium chloride, Triamcinolone, and Acetaminophen. ' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 19:59:56
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:53:52
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:53:49
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:13:10
Outcome

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'PV Query: Please provide the final event outcome, for generalized rash skin eruption when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 12:59:41
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:11:50
Query 'PV Query: Please provide the final event outcome, for generalized rash skin eruption when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 20:08:10
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 20:08:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information		01 Apr 2021 20:08:01
User opened query 'PV Query: Please provide the final event outcome, for generalized rash skin eruption when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		30 Mar 2021 13:19:23
User closed query 'PV Query: Please provide the final event outcome, when available for even #3, rash skin eruption. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 15:26:13
Query 'PV Query: Please provide the final event outcome, when available for even #3, rash skin eruption. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'WILL DO' (Site from Safety).	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 21:02:29

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Outcome

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available for even #3, rash skin eruption. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:03:57
Query 'Please clarify per source this has a # 2 for outcome of Recovered/Resolved. Has AE resolved?' canceled (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 19:54:44
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:53:47
User opened query 'Please clarify per source this has a # 2 for outcome of Recovered/Resolved. Has AE resolved?' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 19:53:40
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:52:28
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'PV Query: Please deleted event of skin rash eruption since it was confirmed to be the same event as disseminated vesicular rash.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 15:26:16
Query 'PV Query: Please deleted event of skin rash eruption since it was confirmed to be the same event as disseminated vesicular rash.' answered with 'Those are 2 different events.please refer to the 2 previous AE's terminology was updated based on medical records' (Site from Safety).	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 21:02:31
User opened query 'PV Query: Please deleted event of skin rash eruption since it was confirmed to be the same event as disseminated vesicular rash.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:48:55
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:52:26
User entered 'DATA OBTAINED FROM SUBJECTS MEDICAL RECORDS WHICH HAVE BEEN REDACTED AND SUBMITTED TO SAFETY.'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:10

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

AEID

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 15:30:30
Un-reviewed for Safety.		19 Feb 2021 15:30:25
Reviewed for Safety.		19 Feb 2021 15:29:40
Un-reviewed for Safety.		19 Feb 2021 15:29:37
DataPoint Verified.		16 Dec 2020 15:00:20
Reviewed for Safety.		09 Dec 2020 17:51:48
User entered 'USA-US066-2020-mRNA-1273-P301000009'	System	09 Dec 2020 17:51:41
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 17:51:41
User entered 'USA-US066-2020-mRNA-1273-P301000005'	(b) (4), (b) (6)	09 Dec 2020 17:27:11

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'Per MM: Please update to reflect the etiology, if known. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 07:23:07
Query 'Per MM: Please update to reflect the etiology, if known. ' answered with 'Correct as entered, event part of medical history.' (Site from DM).	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 14:37:07
User opened query 'Per MM: Please update to reflect the etiology, if known. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 18:17:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:21:09
User closed query 'Per MM requery-Response noted as 'Yes performed on Nov 30, 2020',however no data is recorded on 'Covid-19 Assessment ' form.Kindly consider to verify and update data appropriately else please clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 07:01:56
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 18:10:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 18:10:05
Query 'Per MM requery-Response noted as 'Yes performed on Nov 30, 2020',however no data is recorded on 'Covid-19 Assessment ' form.Kindly consider to verify and update data appropriately else please clarify.' answered with 'Medical records received, terminoly was changed accordantly.' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:09:22
Data point term sent to Coder	System	19 Feb 2021 18:09:14
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:08:40
Coding entries removed.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:08:40
User entered 'BILATERAL PULMONARY EMBOLISM' reason for change: Per Query Resolution	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:08:40

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Adverse event

Audit	User	Time (GMT)
User opened query 'Per MM requery-Response noted as 'Yes performed on Nov 30, 2020',however no data is recorded on 'Covid-19 Assessment ' form.Kindly consider to verify and update data appropriately else please clarify.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 05:30:31
User closed query 'Per MM, please confirm if the subject was also evaluated for COVID-19.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 05:30:31
Query 'Per MM, please confirm if the subject was also evaluated for COVID-19.' answered with 'Yes performed on Nov 30, 2020' (Site from DM).	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 21:04:26
User opened query 'Per MM, please confirm if the subject was also evaluated for COVID-19.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 07:42:57
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:22
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Dec 2020 18:50:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Dec 2020 18:50:51
Data point term sent to Coder	System	08 Dec 2020 18:50:04
User entered 'Pulmonary Embolism'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:23
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:25
User entered 'No (N)'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:27
User entered 'No (N)'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:31
User entered '29 Nov 2020'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:32
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	08 Dec 2020 18:49:31

US3352299
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 17:13:10
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:34
User entered 'No (N)'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:36
User entered '1 Dec 2020'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:37
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Severity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:40
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Surisaday Mederos (b) (4) (b) (4)	09 Dec 2020 20:00:23
User entered 'Grade 3/Severe (Grade 3/Severe)'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:43
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	09 Dec 2020 20:01:21
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	08 Dec 2020 18:49:31
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:46
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:48
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:50
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).	System	09 Dec 2020 20:09:30
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).	System	09 Dec 2020 20:09:30
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	09 Dec 2020 20:01:21
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	09 Dec 2020 20:01:21
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	09 Dec 2020 20:01:21
User entered '1' reason for change: Data Entry Error	Surisaday Mederos (b) (4) (b) (4)	09 Dec 2020 20:01:21
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	08 Dec 2020 18:49:31
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:51
User entered '29 Nov 2020'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:52
User entered '1 Dec 2020'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:21:34
User closed query 'Per CDM Per previous query response,Pending medical records at this time,kindly consider to update data to Yes or No, whenever data is available.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 07:03:41
Query 'Per CDM Per previous query response,Pending medical records at this time,kindly consider to update data to Yes or No, whenever data is available.' answered with 'Medical records will be submitted.' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:09:52
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:08:40
User entered 'No (N)' reason for change: Data Entry Error	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:08:40
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	21 Jan 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:54
User opened query 'Per CDM Per previous query response,Pending medical records at this time,kindly consider to update data to Yes or No, whenever data is available.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:38:23
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'Pending medical records at this time. ' (Site from System).	Surisaday Mederos (b) (4) (b) (4)	09 Dec 2020 20:10:11
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	09 Dec 2020 20:09:30
User entered 'Unknown (UNK)' reason for change: Data Entry Error	Surisaday Mederos (b) (4) (b) (4)	09 Dec 2020 20:09:30
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:56
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:00:58
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:01:00
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:01:02
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:01:04
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 02:05:51
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'Not related to study product. Subject had a similar event in 2018. ' (Site from Safety).	Surisaday Mederos (b) (4) (b) (4)	09 Dec 2020 20:09:24
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 20:00:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 20:00:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Surisaday Mederos (b) (4) (b) (4)	09 Dec 2020 20:00:23
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 17:26:24
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 18:49:31
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

FDA-CBER-2022-1614-0966420

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:01:07
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 20:00:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 20:00:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Surisaday Mederos (b) (4) (b) (4)	09 Dec 2020 20:00:23
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 18:49:31
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:01:08
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 20:00:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 20:00:23
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Surisaday Mederos (b) (4) (b) (4)	09 Dec 2020 20:00:23
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 18:49:31
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

None

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:01:10
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Dec 2020 20:00:23
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	08 Dec 2020 18:49:31
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is BLOOD THINNER. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 07:07:30
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is BLOOD THINNER. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' answered with 'Xarelto was given for the bilateral pulmonary embolism. ' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:11:37
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is BLOOD THINNER. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 06:15:29
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:01:12
User entered '1' reason for change: Data Entry Error	Surisaday Mederos (b) (4) (b) (4)	09 Dec 2020 20:00:23
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

FDA-CBER-2022-1614-0966424

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:01:13
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 17:13:10
Outcome

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:01:16
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 20:02:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 20:02:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Surisaday Mederos (b) (4) (b) (4)	09 Dec 2020 20:02:44
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 18:49:31
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:01:17
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
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) (6)	26 Feb 2021 15:29:05
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)	26 Feb 2021 15:29:03
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 'SARS-CoV-2 Negative 11/30/20 ' (Site from Safety).	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:22:40
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'D-Dimer 2.26 mcg/ml performed11/29/20. PTT 49.7 seconds. ' (Site from Safety).	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:20:27
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:01:20
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)	15 Dec 2020 15:28:00
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)	15 Dec 2020 15:27:33
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Dec 2020 20:00:23
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	09 Dec 2020 20:00:23

US3352299
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 17:13:10
Narrative

Audit	User	Time (GMT)
User entered 'Subject have a history of Pulmonary Embolism, this incident occured after he came back from a trip, he is now taken Xarelto 15 mg. Subject is currently doing well.' reason for change: Data Entry Error	Surisaday Mederos (b) (4) (b) (4)	09 Dec 2020 20:00:23
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	08 Dec 2020 18:49:31
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:49:31

FDA-CBER-2022-1614-0966429

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 18:49:31

US3352299

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 18:49:31

Audit	User	Time (GMT)
User entered '0'	System	09 Dec 2020 20:09:30

US3352299
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:13:10
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User closed query 'Per MM, please confirm if the subject was evaluated for COVID-19 ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 07:23:26
Query 'Per MM, please confirm if the subject was evaluated for COVID-19 ' answered with 'Yes.' (Site from DM).	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 14:40:14
User opened query 'Per MM, please confirm if the subject was evaluated for COVID-19 ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 18:17:43
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 18:29:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 18:29:04
Data point term sent to Coder	System	19 Feb 2021 18:28:32
User entered 'Pneumonia'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:13:10
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered 'Yes (Y)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered '29 Nov 2020'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User entered empty.	System	19 Feb 2021 18:27:52

US3352299
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:13:10
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered '1 Dec 2020'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:13:10
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User entered empty.	System	19 Feb 2021 18:27:52

FDA-CBER-2022-1614-0966444

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered 'Grade 1/Mild (Grade 1/Mild)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:13:10
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:13:10
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 07:12:45
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'This AE was not the reason of the hospitalization. ' (Site from System).	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:28:33
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	19 Feb 2021 18:27:52
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:13:10
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:13:10
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:13:10
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered 'None (NONE)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:13:10
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:13:10
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered '1'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:13:10
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:48:03
User entered 'Subject had a bilateral pulmonary embolism November 29, 2020. Pneumonia was part of the reportable conditions upon medical records reviewed.'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:27:52

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User entered '0'	System	19 Feb 2021 18:27:52

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User entered '1'	System	19 Feb 2021 18:27:52

US3352299

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:10

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:59
User entered '0'	System	19 Feb 2021 18:27:52

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:13:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:01:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:09:35

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
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 SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:11:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:11:46
Data point term sent to Coder	System	01 Sep 2020 18:10:50
User entered 'SYNTHROID'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'HYPOTHYROIDISM'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '200'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:58:36
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'data updated' (Site from DM).	Matthew Muniz (b) (4)	29 Oct 2020 18:03:53
User entered 'ug (ug)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	29 Oct 2020 18:03:33
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 07:37:33
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'UN UNK 2005'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

FDA-CBER-2022-1614-0966484

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, POTENT (GROUP III), PRODUCT: BETAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 12:07:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 12:07:29
Data point term sent to Coder	System	20 Mar 2021 14:34:45
Data point term sent to Coder	System	20 Mar 2021 14:33:43
Coding entries removed.	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 14:33:33
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, POTENT (GROUP III), PRODUCT: BETAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:18:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:18:03
Data point term sent to Coder	System	22 Feb 2021 18:00:05
Coding entries removed.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:59:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:05:12
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, POTENT (GROUP III), PRODUCT: BETAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:02:59

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
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 Nov 2020 20:02:59
Data point term sent to Coder	System	24 Nov 2020 18:53:17
User entered 'BETHAMETHASONE 0.05%'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:05:13
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:13:10
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:35:07
User closed query 'If this medication is for Disseminated Vesicular Reaction, then this needs to have the same end date of 13-NOV-2020 as Disseminated Vesicular Reaction. If this is ended on 15DEC2020 then subject is not taking it for Disseminated Vesicular Reaction, subject is taking it for something else, subject can not continue a medication for an AE that has ended. Please clarify.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 15:35:05
Query 'If this medication is for Disseminated Vesicular Reaction, then this needs to have the same end date of 13-NOV-2020 as Disseminated Vesicular Reaction. If this is ended on 15DEC2020 then subject is not taking it for Disseminated Vesicular Reaction, subject is taking it for something else, subject can not continue a medication for an AE that has ended. Please clarify.' answered with 'updated' (Site from CRA).	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 14:33:59
User entered 'GENERALIZED RASK SKIN ERUPTION' reason for change: Per Query Resolution	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 14:33:54
DataPoint Un-verified.	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 14:33:33
User entered 'Generalized rask skin sruption' reason for change: Per Query Resolution	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 14:33:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User opened query 'If this medication is for Disseminated Vesicular Reaction, then this needs to have the same end date of 13-NOV-2020 as Disseminated Vesicular Reaction. If this is ended on 15DEC2020 then subject is not taking it for Disseminated Vesicular Reaction, subject is taking it for something else, subject can not continue a medication for an AE that has ended. Please clarify.' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 19:32:47

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Query 'If this medication is for Disseminated Vesicular Rash, then this needs to have the same end date of 13-NOV-2020 as Disseminated Vesicular Rash. If this is ended on 15DEC2020 then subject is not taking it for Disseminated Vesicular Rash, subject is taking it for something else, subject can not continue a medication for an AE that has ended. Please clarify.' canceled (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 19:32:18
User opened query 'If this medication is for Disseminated Vesicular Rash, then this needs to have the same end date of 13-NOV-2020 as Disseminated Vesicular Rash. If this is ended on 15DEC2020 then subject is not taking it for Disseminated Vesicular Rash, subject is taking it for something else, subject can not continue a medication for an AE that has ended. Please clarify.' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 19:31:29
User closed query 'Per DM CLR Requery-Response noted as 'AE Terminology confirmed.',however,in the Ae Form,It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 06:53:42
Query 'Per DM CLR Requery-Response noted as 'AE Terminology confirmed.',however,in the Ae Form,It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' answered with 'Data updated' (Site from DM).	Wanda Delgado (b) (4)	05 Mar 2021 17:40:57
User opened query 'Per DM CLR Requery-Response noted as 'AE Terminology confirmed.',however,in the Ae Form,It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 05:51:13

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 05:51:13
Query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:59:34
' answered with 'AE Terminology confirmed.' (Site from DM).		
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:59:29
User entered 'DISSEMINATED VESICULAR Reaction' reason for change: Per Query Resolution	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:59:29
User opened query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.	(b) (4), (b) (6)	16 Dec 2020 01:23:07
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:05:17
User entered 'DISSEMINATED VESICULAR RASH'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:05:18
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:05:20
User entered 'Other (OTHER)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:05:21
User entered 'APPLICATION'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:05:23
User entered 'twice daily (BID)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:05:24
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:05:26
User entered 'Topical (TOPICAL)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:05:27
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:05:29
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:05:30
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:32:53
Query 'If this medication is for Disseminated Vesicular Rash, then this needs to have the same end date of 13-NOV-2020. If this is ongoing then subject is not taking it for Vesicular rash, subject is taking it for something else, subject can not continue a medication for an AE that has ended. Please clarify.' canceled (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 19:30:06
User opened query 'If this medication is for Disseminated Vesicular Rash, then this needs to have the same end date of 13-NOV-2020. If this is ongoing then subject is not taking it for Vesicular rash, subject is taking it for something else, subject can not continue a medication for an AE that has ended. Please clarify.' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 19:28:19
User closed query 'Please clarify if this is ongoing, the AE if Disseminated Vesicular rash ended on 13-Nov-2020.' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 19:28:19
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 18:00:07
User entered 'No (N)' reason for change: Per Query Resolution	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 18:00:07
Query 'Please clarify if this is ongoing, the AE if Disseminated Vesicular rash ended on 13-Nov-2020.' answered with 'subject started con med on 11/13/2020, still ongoing ' (Site from CRA).	Wanda Delgado (b) (4)	04 Dec 2020 16:34:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:05:32
User opened query 'Please clarify if this is ongoing, the AE if Disseminated Vesicular rash ended on 13-Nov-2020.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:05:01
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:32:55
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 18:00:07
User entered '15 Dec 2020' reason for change: New Information	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 18:00:07
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:05:34
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:05:35
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:49
User entered '2'	System	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:49
User entered '1'	System	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:49
User entered '804 (804)'	System	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:36:12
User closed query 'Please correct spelling to Prednisone ' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 19:36:10
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:39:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:39:08
Query 'Please correct spelling to Prednisone ' answered with 'confirmed.' (Site from CRA).	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 18:01:38
Data point term sent to Coder	System	22 Feb 2021 18:01:29
Coding entries removed.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 18:01:22
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 18:01:22
Coding entries removed.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 18:01:22
User entered 'PREdnisone' reason for change: Per Query Resolution	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 18:01:22
User opened query 'Please correct spelling to Prednisone ' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 15:14:40
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 20:42:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 20:42:04

PRODUCTION RELEASE (v12.003 EAB) (1725)

2015 of 2877

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data point term sent to Coder	System	10 Dec 2020 20:00:31
Coding entries removed.	Matthew Muniz (b) (4)	10 Dec 2020 19:59:32
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:07:53
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:47:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:47:30
Data point term sent to Coder	System	24 Nov 2020 19:50:43
User entered 'PREDISONE'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:07:56
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:36:16
User closed query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 05:52:16
Query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'AE Terminology confirmed.' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 18:01:41
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 18:01:22
User entered 'Generalized RASH SKIN ERUPTION' reason for change: Data Entry Error	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 18:01:22
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:03:06
User opened query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 01:27:04
DataPoint Un-verified.	Matthew Muniz (b) (4)	10 Dec 2020 19:59:32
User entered 'Rash Skin Eruption' reason for change: Data Entry Error	Matthew Muniz (b) (4)	10 Dec 2020 19:59:32
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:07:58
User entered 'DISSEMINATED VESICULAR RASH'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:08:00
User entered '40'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:08:06
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:08:09
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:08:15
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	24 Nov 2020 21:01:00
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	24 Nov 2020 21:01:00
User entered 'once daily (QD)' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 21:01:00
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	24 Nov 2020 19:49:53
User entered 'once (ONCE)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:08:16
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:08:17
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:08:19
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:08:21
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:08:24
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:08:26
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'Please clarify if this is for AE of Disseminated Vesicular Rash or for Rash Skin Eruption? Disseminated Vesicular Rash ended on 13-Nov-2020 how could this be indicated for this AE? Please clarify in EDC and source. ' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 15:50:30
Query 'Please clarify if this is for AE of Disseminated Vesicular Rash or for Rash Skin Eruption? Disseminated Vesicular Rash ended on 13-Nov-2020 how could this be indicated for this AE? Please clarify in EDC and source. ' answered with 'updated' (Site from CRA).	Matthew Muniz (b) (4)	10 Dec 2020 19:59:46
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:13:02
User opened query 'Please clarify if this is for AE of Disseminated Vesicular Rash or for Rash Skin Eruption? Disseminated Vesicular Rash ended on 13-Nov-2020 how could this be indicated for this AE? Please clarify in EDC and source. ' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:12:57
Query 'Please clarify if this is for AE of Disseminated Vesicular Rash or for Rash Skin Eruption? Disseminated Vesicular Rash ended on 13-Nov-2020 how could this be indicated for this AE?' canceled (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:12:24
User opened query 'Please clarify if this is for AE of Disseminated Vesicular Rash or for Rash Skin Eruption? Disseminated Vesicular Rash ended on 13-Nov-2020 how could this be indicated for this AE?' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:12:02
User entered '15 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:13:04
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:52
User entered '1'	System	24 Nov 2020 21:01:00
User entered empty.	System	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:52
User entered '1'	System	24 Nov 2020 21:01:00
User entered empty.	System	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:52
User entered '804 (804)'	System	24 Nov 2020 21:01:00
User entered empty.	System	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR HYDROCHLORIDE, PRODUCTSYNONYM: VALTREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:04:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:04:01
Data point term sent to Coder	System	22 Feb 2021 18:02:56
Coding entries removed.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 18:02:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR HYDROCHLORIDE, PRODUCTSYNONYM: VALTREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 20:01:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 20:01:54
Data point term sent to Coder	System	10 Dec 2020 20:01:33
Coding entries removed.	Matthew Muniz (b) (4)	10 Dec 2020 20:00:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:13:31

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR HYDROCHLORIDE, PRODUCTSYNONYM: VALTREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:53:07
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 Nov 2020 19:53:07
Data point term sent to Coder	System	24 Nov 2020 19:51:44
User entered 'VALTREX'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:13:33
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User closed query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:11:32
Query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'AE Terminology confirmed.' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 18:02:33
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 18:02:28
User entered 'Genralized RASH SKIN ERUPTION' reason for change: Per Query Resolution	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 18:02:28
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:03:17
User opened query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 01:27:43
DataPoint Un-verified.	Matthew Muniz (b) (4)	10 Dec 2020 20:00:36
User entered 'Rash Skin Eruption' reason for change: Data Entry Error	Matthew Muniz (b) (4)	10 Dec 2020 20:00:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:13:37
User entered 'DISSEMINATED VESICULAR RASH'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:13:39
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:13:41
User entered 'g (g)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:13:44
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:13:46
User entered 'three times daily (TID)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:13:48
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:13:50
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:13:56
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:13:59
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:14:01
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:14:03
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'Please clarify if this is for AE of Disseminated Vesicular Rash or for Rash Skin Eruption? Disseminated Vesicular Rash ended on 13-Nov-2020 how could this be indicated for this AE, is the AE ongoing? Please clarify in EDC and source. ' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 16:04:16
Query 'Please clarify if this is for AE of Disseminated Vesicular Rash or for Rash Skin Eruption? Disseminated Vesicular Rash ended on 13-Nov-2020 how could this be indicated for this AE, is the AE ongoing? Please clarify in EDC and source. ' answered with 'Rash Skin Eruption' (Site from CRA).	Matthew Muniz (b) (4)	10 Dec 2020 20:00:48
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:14:55
User opened query 'Please clarify if this is for AE of Disseminated Vesicular Rash or for Rash Skin Eruption? Disseminated Vesicular Rash ended on 13-Nov-2020 how could this be indicated for this AE, is the AE ongoing? Please clarify in EDC and source. ' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:14:46
User entered '15 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:14:57
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:54
User entered '3'	System	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:54
User entered '1'	System	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:54
User entered '804 (804)'	System	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 20:19:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 20:19:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 20:05:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 20:05:02
Data point term sent to Coder	System	22 Feb 2021 17:58:02
Coding entries removed.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:57:22
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:15:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 23:52:11

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
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 Nov 2020 23:52:11
Data point term sent to Coder	System	24 Nov 2020 21:00:32
User closed query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	System	24 Nov 2020 21:00:21
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'Data updated' (Site from System).	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 21:00:21
User entered 'CLARITIN (Loratadine)' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 21:00:09
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:23:55
Data point term sent to Coder	System	24 Nov 2020 20:14:20
User entered 'CLARITIN'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:15:10
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User closed query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:37:12
Query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'AE Terminology confirmed.' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:57:28
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:57:22
User entered 'Generalized RASK SKIN ERUPTION' reason for change: Per Query Resolution	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:57:22
User opened query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 01:35:14
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:15:12
User entered 'RASK SKIN ERUPTION ALL OVER BODY'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:15:15
User entered '10'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:15:20
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:15:23
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:15:25
User entered 'once daily (QD)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:15:28
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:15:31
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:15:33
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:15:35
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:15:38
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:15:39
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:15:41
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:15:50
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:56
User entered '1'	System	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:56
User entered '1'	System	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:58:56
User entered '804 (804)'	System	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
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.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:58:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:58:02
Data point term sent to Coder	System	22 Feb 2021 17:57:00
Coding entries removed.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:16:09
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.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:25:26
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 Nov 2020 20:25:26
Data point term sent to Coder	System	24 Nov 2020 20:23:40
User entered 'DILAUDID'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:16:10
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User closed query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:37:00
Query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'AE Terminology confirmed.' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:56:37
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:56:32
User entered 'Generalized RASH SKIN ERUPTION' reason for change: Per Query Resolution	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:56:32
User opened query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 01:34:49
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:16:20
User entered 'RASH SKIN ERUPTION ALL OVER BODY'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:16:24
User entered '0.5'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:16:35
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:16:37
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:04:43
User closed query 'Per CDM: Please review if frequency 'four times daily' can be selected from drop downlist instead of selecting "Other" and "FOUR TIMES A DAY AS NEEDED". Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 03:34:37
Query 'Per CDM: Please review if frequency 'four times daily' can be selected from drop downlist instead of selecting "Other" and "FOUR TIMES A DAY AS NEEDED". Please review and update accordingly' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	10 Dec 2020 20:03:20
DataPoint Un-verified.	Matthew Muniz (b) (4)	10 Dec 2020 20:03:04
User entered 'four times daily (QID)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	10 Dec 2020 20:03:04
User opened query 'Per CDM: Please review if frequency 'four times daily' can be selected from drop downlist instead of selecting "Other" and "FOUR TIMES A DAY AS NEEDED". Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 07:37:13
Query 'Please review if frequency 'four times daily' can be selected from drop downlist instead of selecting "Other" and "FOUR TIMES A DAY AS NEEDED". Please review and update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 07:36:57
User opened query 'Please review if frequency 'four times daily' can be selected from drop downlist instead of selecting "Other" and "FOUR TIMES A DAY AS NEEDED". Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 07:02:04
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:16:44
User entered 'other (OTHER)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:04:45
DataPoint Un-verified.	Matthew Muniz (b) (4)	10 Dec 2020 20:03:04
User entered empty; reason for change Data Entry Error	Matthew Muniz (b) (4)	10 Dec 2020 20:03:04
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:16:53
User entered 'FOUR TIMES A DAY AS NEEDED'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:16:55
User entered 'Other (OTHER)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:17:07
User entered 'INTRAVENOUS PUSH'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:17:12
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:17:14
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:17:21
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:17:23
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:17:24
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:00
User entered '4'	System	10 Dec 2020 20:03:04
User entered empty.	System	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:00
User entered '1'	System	10 Dec 2020 20:03:04
User entered empty.	System	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:00
User entered '804 (804)'	System	10 Dec 2020 20:03:04
User entered empty.	System	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: OTHER DERMATOLOGICALS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:31:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:31:02
Data point term sent to Coder	System	22 Feb 2021 17:38:26
Coding entries removed.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:38:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:19:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: OTHER AGENTS FOR LOCAL ORAL TREATMENT, PRODUCT: ALUMINIUM HYDROXIDE;DIPHENHYDRAMINE;LIDOCAINE;MAGNESIUM HYDROXIDE;SIMETICONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 04:44:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 04:44:55
Data point term sent to Coder	System	24 Nov 2020 20:26:43
User entered 'ALUMINUM HYDROXIDE/ DIPHENHYDRAMINE/ LIDOCAINE/ MAGNESIUM HYDROXIDE/ SIMETHICORE TOPICAL'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:19:04
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User closed query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:16:50
Query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' answered with 'Confirmed AE terminology.' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:39:31
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:38:25
User entered 'Generalized Rash Skin Eruption' reason for change: New Information	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:38:25
User opened query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 01:28:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:19:06
User entered 'RASH SKIN ALL OVER BODY'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:27:05
User closed query 'Source states 40 and 5 ml. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:27:03
Query 'Source states 40 and 5 ml. Please review and reconcile. ' answered with 'UPDATED' (Site from CRA).	Matthew Muniz (b) (4)	14 Apr 2021 15:37:30
User entered '40/5' reason for change: Data Entry Error	Matthew Muniz (b) (4)	14 Apr 2021 15:37:24
User opened query 'Source states 40 and 5 ml. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 14:11:56
User closed query 'Per DM CLR: Please review if the number of applications administered is to be recorded for a topical medication. If so, update entry as appropriate (eg, Dose-1, Dose Unit-Application). ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 20:02:33
Query 'Per DM CLR: Please review if the number of applications administered is to be recorded for a topical medication. If so, update entry as appropriate (eg, Dose-1, Dose Unit-Application). ' answered with 'dose corrected' (Site from DM).	Yulexis Amestoy (b) (4) (b) (4)	07 Apr 2021 14:55:55
DataPoint Un-verified.	Yulexis Amestoy (b) (4) (b) (4)	07 Apr 2021 14:55:38
User entered '5' reason for change: Data Entry Error	Yulexis Amestoy (b) (4) (b) (4)	07 Apr 2021 14:55:38
User opened query 'Per DM CLR: Please review if the number of applications administered is to be recorded for a topical medication. If so, update entry as appropriate (eg, Dose-1, Dose Unit-Application). ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:12:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:19:11
User entered '40'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:19:13
User entered 'mL (mL)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:19:15
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:19:16
User entered 'other (OTHER)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:19:18
User entered 'EVERY THREE HOURS'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:19:20
User entered 'Topical (TOPICAL)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:19:22
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:19:24
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:19:27
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:19:28
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:19:29
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:19:31
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:04
User entered empty.	System	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:04
User entered empty.	System	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:04
User entered empty.	System	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:12
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, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 22:37:05
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 Nov 2020 22:37:05
Data point term sent to Coder	System	24 Nov 2020 20:27:45
User entered 'PEPCID'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:16
User entered 'GASTRIC PROPHYLAXIS'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:23
User entered '20 / 2'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:25
User entered 'Other (OTHER)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:27
User entered 'MG / ML'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:29
User entered 'twice daily (BID)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:33
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:31
User entered 'Intravenous (INTRAVENOUS)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:35
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:36
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:38
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:39
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:08
User entered '2'	System	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:08
User entered '1'	System	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:08
User entered '804 (804)'	System	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:59:19
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:39:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:39:09
Data point term sent to Coder	System	22 Feb 2021 17:41:29
Coding entries removed.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:40:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:47:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:47:29
Data point term sent to Coder	System	24 Nov 2020 20:28:45
User entered 'PREDNISONE'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:59:19
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:59:19
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User closed query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:35:34
Query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'Confirmed AE terminology.' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:42:34
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:40:33
User entered 'Generalized Rash Skin Eruption.' reason for change: Data Entry Error	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:40:33
User opened query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 01:31:03
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:59:19
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '10'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:59:19
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:59:19
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:59:19
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'once daily (QD)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:59:19
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:59:19
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:59:19
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:59:19
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '21 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:59:19
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:59:19
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:59:19
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:59:19
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:59:19
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:13
User entered '1'	System	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:59:19
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:13
User entered '1'	System	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:59:19
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:13
User entered '804 (804)'	System	24 Nov 2020 20:28:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:47:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:47:11
Data point term sent to Coder	System	22 Feb 2021 17:45:35
Coding entries removed.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:45:03
User closed query 'Please correct spelling to Hydromorphone vs Hycromorphone' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 16:05:15
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:05:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 00:37:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 00:37:46
Query 'Please correct spelling to Hydromorphone vs Hycromorphone' answered with 'Data updated ' (Site from CRA).	Wanda Delgado (b) (4)	04 Dec 2020 16:02:51
Data point term sent to Coder	System	04 Dec 2020 16:02:39
DataPoint Un-verified.	Wanda Delgado (b) (4)	04 Dec 2020 16:01:57
Coding entries removed.	Wanda Delgado (b) (4)	04 Dec 2020 16:01:57
User entered 'Hydromorphone' reason for change: Data Entry Error	Wanda Delgado (b) (4)	04 Dec 2020 16:01:57

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
User opened query 'Please correct spelling to Hydromorphone vs Hycromorphone' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:22:50
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:49:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:49:04
Data point term sent to Coder	System	24 Nov 2020 20:32:51
User entered 'HYCHROMORPHONE'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User closed query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:20:23
Query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'Confirmed AE terminology.' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:45:27
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:45:03
User entered 'Generalized Rash Skin Eruption' reason for change: Per Query Resolution	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:45:03
User opened query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 01:29:53
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '0.5'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'once (ONCE)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'Intravenous (INTRAVENOUS)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:27
User entered empty.	System	24 Nov 2020 20:32:49

FDA-CBER-2022-1614-0966654

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:27
User entered empty.	System	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:27
User entered empty.	System	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:05:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:05:00
Data point term sent to Coder	System	22 Feb 2021 17:47:44
Coding entries removed.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:46:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:48:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:48:01
Data point term sent to Coder	System	24 Nov 2020 20:33:52
User entered 'ONDANSETRON'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User closed query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:22:53
Query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'Confirmed AE terminonology.' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:47:15
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:46:47
User entered 'Generalized RASH SKIN ERUPTION' reason for change: Per Query Resolution	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:46:47
User opened query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 01:30:18
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '4'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'once (ONCE)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'Intravenous (INTRAVENOUS)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:31
User entered empty.	System	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:31
User entered empty.	System	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:31
User entered empty.	System	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:39:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:39:08
Data point term sent to Coder	System	22 Feb 2021 17:47:44
Coding entries removed.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:47:41
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:47:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:47:29
Data point term sent to Coder	System	24 Nov 2020 20:34:54
User entered 'PREDNISONE'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User closed query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:35:57
Query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'AE terminology confirmed.' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:47:56
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:47:41
User entered 'Generalized RASH SKIN ERUPTION' reason for change: Per Query Resolution	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:47:41
User opened query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 01:31:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '30'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	24 Nov 2020 21:01:19
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	24 Nov 2020 21:01:19
User entered 'once daily (QD)' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 21:01:19
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	24 Nov 2020 20:34:33
User entered 'once (ONCE)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '16 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '18 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:36
User entered '1'	System	24 Nov 2020 21:01:19
User entered empty.	System	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:36
User entered '1'	System	24 Nov 2020 21:01:19
User entered empty.	System	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:36
User entered '804 (804)'	System	24 Nov 2020 21:01:19
User entered empty.	System	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:40
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:39:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:39:09
Data point term sent to Coder	System	22 Feb 2021 17:48:45
Coding entries removed.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:48:38
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:47:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:47:30
Data point term sent to Coder	System	24 Nov 2020 20:35:55
User entered 'PREDNISONE'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:40
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:40
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User closed query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:36:21
Query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'AE Terminology confirmed.' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:48:44
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:48:38
User entered 'Generalized RASH SKIN ERUPTION' reason for change: Per Query Resolution	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:48:38
User opened query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 01:31:43
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:40
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '20'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:40
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:40
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:40
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	24 Nov 2020 21:01:32
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	24 Nov 2020 21:01:32
User entered 'once daily (QD)' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 21:01:32
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	24 Nov 2020 20:35:54
User entered 'once (ONCE)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:40
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:40
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:40
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:40
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '19 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:40
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:40
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:40
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '20 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:40
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:40
User entered '1'	System	24 Nov 2020 21:01:32
User entered empty.	System	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:40
User entered '1'	System	24 Nov 2020 21:01:32
User entered empty.	System	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:40
User entered '804 (804)'	System	24 Nov 2020 21:01:32
User entered empty.	System	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:39:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:39:09
Data point term sent to Coder	System	22 Feb 2021 17:49:47
Coding entries removed.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:49:01
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:47:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:47:30
Data point term sent to Coder	System	24 Nov 2020 20:37:56
User entered 'PREDNISONE'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User closed query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:36:27
Query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'AE Terminology confirmed.' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:49:08
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:49:01
User entered 'Generalized RASH SKIN ERUPTION' reason for change: Per Query Resolution	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:49:01
User opened query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 01:32:05
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '100'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'twice daily (BID)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '12 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:44
User entered '2'	System	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:44
User entered '1'	System	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:44
User entered '804 (804)'	System	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:20:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:20:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:10:43
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 Mar 2021 00:10:43
Data point term sent to Coder	System	22 Feb 2021 17:49:47
Coding entries removed.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:49:32
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:38:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:38:09

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data point term sent to Coder	System	24 Nov 2020 20:42:00
User entered 'SODIUM CHLORIDE 0.9%'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User closed query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:36:32
Query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'AE Terminology confirmed.' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:49:38
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:49:32
User entered 'Generalized RASH SKIN ERUPTION' reason for change: Per Query Resolution	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:49:32
User opened query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 01:33:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '1000'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'mL (mL)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	24 Nov 2020 21:02:01
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	24 Nov 2020 21:02:01
User entered 'once daily (QD)' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 21:02:01
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	24 Nov 2020 21:01:54
User entered 'once (ONCE)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'Intravenous (INTRAVENOUS)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	24 Nov 2020 21:01:54
User entered '12 Nov 2020' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 21:01:54
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	24 Nov 2020 20:41:21
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:49
User entered '1'	System	24 Nov 2020 21:02:01
User entered empty.	System	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:49
User entered '1'	System	24 Nov 2020 21:02:01
User entered empty.	System	24 Nov 2020 20:41:21

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:49
User entered '804 (804)'	System	24 Nov 2020 21:02:01
User entered empty.	System	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:03:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:03:57
Data point term sent to Coder	System	22 Feb 2021 17:50:48
Coding entries removed.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:49:56
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 23:01:11
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 Nov 2020 23:01:11
Data point term sent to Coder	System	24 Nov 2020 20:47:13
User entered 'TRIAMCINOLONE 0.01%'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User closed query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:36:38
Query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'AE Terminology confirmed.' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:50:02
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:49:56
User entered 'Generalized RASH SKIN ERUPTION' reason for change: Per Query Resolution	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:49:56
User opened query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 01:33:42
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'Other (OTHER)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'APPLICATION'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'three times daily (TID)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'Topical (TOPICAL)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:53
User entered '3'	System	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:53
User entered '1'	System	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:53
User entered '804 (804)'	System	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:53:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:53:00
Data point term sent to Coder	System	22 Feb 2021 17:52:53
Coding entries removed.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:52:39
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:49:06
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 Nov 2020 20:49:06
Data point term sent to Coder	System	24 Nov 2020 20:48:14
User entered 'ACETAMINOPHEN'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:41:31
User closed query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:19:30
Query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'AE Terminology confirmed.' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:52:45
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:52:39
User entered 'Generalized RASH SKIN ERUPTION' reason for change: Per Query Resolution	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:52:39
User opened query 'Per DM CLR: This Conmed is given for the AE#4. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 01:29:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '1000'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'once (ONCE)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:59
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:20:43
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:59
User entered empty.	System	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:59
User entered empty.	System	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:59:59
User entered empty.	System	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:55:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:55:01
Data point term sent to Coder	System	22 Feb 2021 17:53:56
Coding entries removed.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:53:41
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:39:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 18:51:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 18:51:52
Data point term sent to Coder	System	08 Dec 2020 18:51:05
User entered 'Xarelto'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:50:41

FDA-CBER-2022-1614-0966784

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:39:46
User entered 'No (N)'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:50:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:39:58
User closed query 'Per source this is for Cardiac Prophylaxis, please clarify. ' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 19:39:56
Query 'Per source this is for Cardiac Prophylaxis, please clarify. ' answered with 'Confirmed different indication.' (Site from CRA).	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:54:06
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:53:41
User entered 'Pulmonay Embolism' reason for change: New Information	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:53:41
User opened query 'Per source this is for Cardiac Prophylaxis, please clarify. ' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 15:54:03
Query 'Please clarify if this is for the AE of Pulmonary Embolism which has an end date of 01DEC2020 or a Cardiac Prophylaxis?' canceled (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 15:53:38
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:48:07
User opened query 'Please clarify if this is for the AE of Pulmonary Embolism which has an end date of 01DEC2020 or a Cardiac Prophylaxis?' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 15:46:32
User entered 'Blood thinner'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:50:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:42:50
User entered '15'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:50:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:42:52
User entered 'mg (mg)'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:50:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:42:54
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:50:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:42:56
User entered 'twice daily (BID)'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:50:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:42:57
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:50:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:42:59
User entered 'Oral (ORAL)'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:50:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:43:02
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:50:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:43:05
User entered '29 Nov 2020'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:50:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:43:07
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:50:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:40:36
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:53:41
User entered 'No (N)' reason for change: Data Entry Error	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:53:41
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:43:09
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:50:41

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 17:13:10
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:40:38
DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:53:41
User entered '15 Dec 2020' reason for change: New Information	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:53:41
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:43:11
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:50:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:43:12
User entered 'No (N)'	Yulexis Amestoy (b) (4) (b) (4)	08 Dec 2020 18:50:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:08
User entered '2'	System	08 Dec 2020 18:50:41

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:08
User entered '1'	System	08 Dec 2020 18:50:41

FDA-CBER-2022-1614-0966800

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:08
User entered '804 (804)'	System	08 Dec 2020 18:50:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 18:33:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 18:33:53
Data point term sent to Coder	System	19 Feb 2021 18:33:13
User entered 'Ceftriaxone'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:33:00

FDA-CBER-2022-1614-0966802

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:33:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'Pneumonia'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:33:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '1000'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:33:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'mg (mg)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:33:00

FDA-CBER-2022-1614-0966806

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:33:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'once (ONCE)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:33:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:33:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'Intravenous (INTRAVENOUS)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:33:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:33:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '29 Nov 2020'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:33:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:33:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:33:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '29 Nov 2020'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:33:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:33:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:16
User entered empty.	System	19 Feb 2021 18:33:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:16
User entered empty.	System	19 Feb 2021 18:33:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:16
User entered empty.	System	19 Feb 2021 18:33:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE 5% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 05:41:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 05:41:47
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
Data point term sent to Coder	System	19 Feb 2021 18:35:16
User entered 'Premix Dextrose 5 %'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:34:55

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:34:55

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'Bilateral Pulmonary Embolism'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:34:55

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '500'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:34:55

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'mL (mL)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:34:55

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:34:55

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'once (ONCE)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:34:55

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:34:55

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'Intravenous (INTRAVENOUS)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:34:55

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:34:55

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '30 Nov 2020'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:34:55

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:34:55

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:34:55

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '30 Nov 2020'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:34:55

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:34:55

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:20
User entered empty.	System	19 Feb 2021 18:34:55

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:20
User entered empty.	System	19 Feb 2021 18:34:55

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:20
User entered empty.	System	19 Feb 2021 18:34:55

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE 5% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 05:41:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 05:41:48
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
Data point term sent to Coder	System	19 Feb 2021 18:38:18
User entered 'Premix Dextrose 5 %'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:37:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:37:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'Bilateral Pulmonary Embolism'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:37:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '26'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:37:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'mL (mL)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:37:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:37:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'other (OTHER)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:37:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'Please clarify, ConMed Log source has QD. ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 15:44:39
Query 'Please clarify, ConMed Log source has QD. ' answered with 'CC med page updated' (Site from CRA).	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 14:30:18
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User opened query 'Please clarify, ConMed Log source has QD. ' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 19:45:34
User entered '26 ml every hour'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:37:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'Intravenous (INTRAVENOUS)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:37:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:37:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '30 Nov 2020'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:37:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:37:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:37:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '1 Dec 2020'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:37:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:37:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:25
User entered empty.	System	19 Feb 2021 18:37:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:25
User entered empty.	System	19 Feb 2021 18:37:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:25
User entered empty.	System	19 Feb 2021 18:37:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 13:56:49
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 Feb 2021 13:56:49
Data point term sent to Coder	System	19 Feb 2021 18:39:19
User entered 'Heparin'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:38:44

FDA-CBER-2022-1614-0966856

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:38:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'Bilateral Pulmonary Embolism'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:38:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
DataPoint Un-verified.	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:01:16
User entered '5000' reason for change: Data Entry Error	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:01:16
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '500'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:38:44

FDA-CBER-2022-1614-0966859

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'mL (mL)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:38:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:38:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'once (ONCE)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:38:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:38:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'Intravenous (INTRAVENOUS)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:38:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:38:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '30 Nov 2020'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:38:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:38:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:38:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '30 Nov 2020'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:38:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:38:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:29
User entered empty.	System	19 Feb 2021 18:38:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:29
User entered empty.	System	19 Feb 2021 18:38:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:29
User entered empty.	System	19 Feb 2021 18:38:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import ^{(b) (4)} (b) (4)	20 Feb 2021 13:56:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import ^{(b) (4)} (b) (4)	20 Feb 2021 13:56:50
Data point term sent to Coder	System	19 Feb 2021 18:41:20
User entered 'Heparin'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:40:23

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:40:23

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'Bilateral Pulmonary Embolism'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:40:23

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'Please clarify per ConMed Log source this is 5000.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 15:43:32
Query 'Please clarify per ConMed Log source this is 5000.' answered with ' 2 different entries are for heparin - refer to that one.' (Site from CRA).	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:03:55
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User opened query 'Please clarify per ConMed Log source this is 5000.' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 19:48:39
User entered '26'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:40:23

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'Please clarify per ConMedLog source this is units. ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 15:43:31
Query 'Please clarify per ConMedLog source this is units. ' answered with ' 2 different entries are for heparin - refer to that one.' (Site from CRA).	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:03:58
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User opened query 'Please clarify per ConMedLog source this is units. ' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 19:49:05
User entered 'mL (mL)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:40:23

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:40:23

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'other (OTHER)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:40:23

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'Please clarify per source ConMed Log this is once. ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 15:43:29
Query 'Please clarify per source ConMed Log this is once. ' answered with ' 2 different entries are for heparin - refer to that one.' (Site from CRA).	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User opened query 'Please clarify per source ConMed Log this is once. ' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 19:46:55
User entered '26 ml per hour'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:40:23

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'Intravenous (INTRAVENOUS)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:40:23

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:40:23

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '30 Nov 2020'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:40:23

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:40:23

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:40:23

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'Per ConMed log this is 30NOV20' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 15:43:27
Query 'Per ConMed log this is 30NOV20' answered with ' 2 different entries are for heparin - refer to that one.' (Site from CRA).	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:04:05
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User opened query 'Per ConMed log this is 30NOV20' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 20:04:14
User entered '1 Dec 2020'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:40:23

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:40:23

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:38
User entered empty.	System	19 Feb 2021 18:40:23

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:38
User entered empty.	System	19 Feb 2021 18:40:23

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:38
User entered empty.	System	19 Feb 2021 18:40:23

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'Per Conmed log source please enter Iopamidol and azithromycin. ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 15:45:18
Query 'Per Conmed log source please enter Iopamidol and azithromycin. ' answered with 'ENTERED' (Site from CRA).	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:13:45
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User opened query 'Per Conmed log source please enter Iopamidol and azithromycin. ' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 20:11:20
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:15:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:15:00
Data point term sent to Coder	System	22 Feb 2021 17:59:03
User entered 'Xarelto'	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:58:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User closed query 'Per CDM: Please confirm if this conmed was used for prevention of indication. If not, kindly update this fiel to NO, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 07:16:02
Query 'Per CDM: Please confirm if this conmed was used for prevention of indication. If not, kindly update this fiel to NO, else provide clarification. ' answered with 'Data updated' (Site from DM).	Wanda Delgado (b) (4)	05 Mar 2021 17:43:24
User entered 'No (N)' reason for change: Data Entry Error	Wanda Delgado (b) (4)	05 Mar 2021 17:43:13
User opened query 'Per CDM: Please confirm if this conmed was used for prevention of indication. If not, kindly update this fiel to NO, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 18:03:42
User entered 'Yes (Y)'	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:58:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication 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)	08 Apr 2021 20:02:48
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication 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 'Related to AE # 5' (Site from DM).	Yulexis Amestoy (b) (4) (b) (4)	07 Apr 2021 15:04:34
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication 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)	05 Apr 2021 15:37:58
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'Pulmonary Embolism'	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:58:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '20'	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:58:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	22 Feb 2021 17:58:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:58:33

FDA-CBER-2022-1614-0966897

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'once daily (QD)'	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:58:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:58:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'Oral (ORAL)'	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:58:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:58:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '16 Dec 2020'	Surisaday Mederos (b) (4)	22 Feb 2021 17:58:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:58:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'Yes (Y)'	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:58:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:58:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:12:14
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 17:58:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 17:58:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 17:58:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Feb 2021 17:58:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 11:08:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 11:08:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
Data point term sent to Coder	System	20 Mar 2021 15:40:16
User entered 'IOPAMIDOL'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:39:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered 'No (N)'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:39:18

FDA-CBER-2022-1614-0966911

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered 'Bilateral Pulmonary embolism'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:39:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered '50'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:39:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered 'mL (mL)'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:39:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered empty.	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:39:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered 'once (ONCE)'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:39:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered empty.	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:39:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered 'Intravenous (INTRAVENOUS)'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:39:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered empty.	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:39:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered '29 Nov 2020'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:39:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered '0'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:39:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered 'No (N)'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:39:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered '29 Nov 2020'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:39:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered 'No (N)'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:39:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:43
User entered empty.	System	20 Mar 2021 15:39:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:43
User entered empty.	System	20 Mar 2021 15:39:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:43
User entered empty.	System	20 Mar 2021 15:39:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Mar 2021 15:42:33
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 Mar 2021 15:42:33
Data point term sent to Coder	System	20 Mar 2021 15:42:17
User entered 'Azithromycin'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:41:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered 'No (N)'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:41:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered 'PNEUMONIA'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:41:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered '500'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:41:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered 'mg (mg)'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:41:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered empty.	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:41:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered 'once (ONCE)'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:41:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered empty.	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:41:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered 'Intravenous (INTRAVENOUS)'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:41:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered empty.	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:41:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered '29 Nov 2020'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:41:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered '0'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:41:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered 'No (N)'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:41:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered '29 Nov 2020'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:41:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:46:07
User entered 'No (N)'	Sara Gomez (b) (4) (b) (4)	20 Mar 2021 15:41:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:49
User entered empty.	System	20 Mar 2021 15:41:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:49
User entered empty.	System	20 Mar 2021 15:41:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:49
User entered empty.	System	20 Mar 2021 15:41:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL DOSEPAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:54:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:54:43
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
Data point term sent to Coder	System	01 Apr 2021 19:19:55
User entered 'Medrol Dose Pak'	(b) (4), (b) (6)	01 Apr 2021 19:19:46

FDA-CBER-2022-1614-0966946

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:19:46

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'bilateral pulmonary embolism'	(b) (4), (b) (6)	01 Apr 2021 19:19:46

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '24'	(b) (4), (b) (6)	01 Apr 2021 19:19:46

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Apr 2021 19:19:46

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:19:46

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'once (ONCE)'	(b) (4), (b) (6)	01 Apr 2021 19:19:46

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:19:46

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Apr 2021 19:19:46

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:19:46

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '01 Dec 2020'	(b) (4), (b) (6)	01 Apr 2021 19:19:46

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:19:46

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:19:46

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	01 Apr 2021 19:20:01
User entered '01 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 19:20:01
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	01 Apr 2021 19:19:46
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:19:46

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:19:46

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:51
User entered empty.	System	01 Apr 2021 19:19:46

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:51
User entered empty.	System	01 Apr 2021 19:19:46

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:51
User entered empty.	System	01 Apr 2021 19:19:46

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL DOSEPAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:54:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:54:43
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
Data point term sent to Coder	System	01 Apr 2021 19:20:56
User entered 'Medrol Dose Pak'	(b) (4), (b) (6)	01 Apr 2021 19:20:39

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:20:39

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'bilateral pulmonary embolism'	(b) (4), (b) (6)	01 Apr 2021 19:20:39

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '20'	(b) (4), (b) (6)	01 Apr 2021 19:20:39

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Apr 2021 19:20:39

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:20:39

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'once (ONCE)'	(b) (4), (b) (6)	01 Apr 2021 19:20:39

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:20:39

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Apr 2021 19:20:39

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:20:39

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '02 Dec 2020'	(b) (4), (b) (6)	01 Apr 2021 19:20:39

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:20:39

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:20:39

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '02 Dec 2020'	(b) (4), (b) (6)	01 Apr 2021 19:20:39

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:20:39

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:56
User entered empty.	System	01 Apr 2021 19:20:39

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:56
User entered empty.	System	01 Apr 2021 19:20:39

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:00:56
User entered empty.	System	01 Apr 2021 19:20:39

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL DOSEPAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:54:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:54:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
Data point term sent to Coder	System	01 Apr 2021 19:21:57
User entered 'Medrol Dose Pak'	(b) (4), (b) (6)	01 Apr 2021 19:21:09

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:21:09

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'bilateral pulmonary embolism'	(b) (4), (b) (6)	01 Apr 2021 19:21:09

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '16'	(b) (4), (b) (6)	01 Apr 2021 19:21:09

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Apr 2021 19:21:09

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 17:13:10
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:21:09

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'once (ONCE)'	(b) (4), (b) (6)	01 Apr 2021 19:21:09

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:21:09

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Apr 2021 19:21:09

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:21:09

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '03 Dec 2020'	(b) (4), (b) (6)	01 Apr 2021 19:21:09

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:21:09

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:21:09

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '03 Dec 2020'	(b) (4), (b) (6)	01 Apr 2021 19:21:09

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:00
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:21:09

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:00
User entered empty.	System	01 Apr 2021 19:21:09

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:00
User entered empty.	System	01 Apr 2021 19:21:09

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:00
User entered empty.	System	01 Apr 2021 19:21:09

FDA-CBER-2022-1614-0966999

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL DOSEPAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:54:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:54:43
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
Data point term sent to Coder	System	01 Apr 2021 19:21:57
User entered 'Medrol Dose Pak'	(b) (4), (b) (6)	01 Apr 2021 19:21:41

FDA-CBER-2022-1614-0967000

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:21:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'bilateral pulmonary embolism'	(b) (4), (b) (6)	01 Apr 2021 19:21:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '12'	(b) (4), (b) (6)	01 Apr 2021 19:21:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Apr 2021 19:21:41

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:21:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'once (ONCE)'	(b) (4), (b) (6)	01 Apr 2021 19:21:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:21:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Apr 2021 19:21:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:21:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '04 Dec 2020'	(b) (4), (b) (6)	01 Apr 2021 19:21:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:21:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:21:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '04 Dec 2020'	(b) (4), (b) (6)	01 Apr 2021 19:21:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:21:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:04
User entered empty.	System	01 Apr 2021 19:21:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:04
User entered empty.	System	01 Apr 2021 19:21:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:04
User entered empty.	System	01 Apr 2021 19:21:41

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL DOSEPAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:54:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:54:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
Data point term sent to Coder	System	01 Apr 2021 19:22:58
User entered 'Medrol Dose Pak'	(b) (4), (b) (6)	01 Apr 2021 19:22:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:22:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'bilateral pulmonary embolism'	(b) (4), (b) (6)	01 Apr 2021 19:22:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '8'	(b) (4), (b) (6)	01 Apr 2021 19:22:21

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Apr 2021 19:22:21

FDA-CBER-2022-1614-0967022

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:22:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'once (ONCE)'	(b) (4), (b) (6)	01 Apr 2021 19:22:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:22:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Apr 2021 19:22:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:22:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '05 Dec 2020'	(b) (4), (b) (6)	01 Apr 2021 19:22:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:22:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:22:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '05 Dec 2020'	(b) (4), (b) (6)	01 Apr 2021 19:22:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:22:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:10
User entered empty.	System	01 Apr 2021 19:22:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:10
User entered empty.	System	01 Apr 2021 19:22:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:10
User entered empty.	System	01 Apr 2021 19:22:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL DOSEPAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:54:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:54:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
Data point term sent to Coder	System	01 Apr 2021 19:24:06
User entered 'Medrol Dose Pak'	(b) (4), (b) (6)	01 Apr 2021 19:23:07

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:23:07

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'bilateral pulmonary embolism'	(b) (4), (b) (6)	01 Apr 2021 19:23:07

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '4'	(b) (4), (b) (6)	01 Apr 2021 19:23:07

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Apr 2021 19:23:07

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:23:07

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'once (ONCE)'	(b) (4), (b) (6)	01 Apr 2021 19:23:07

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:23:07

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Apr 2021 19:23:07

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:23:07

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '06 Dec 2020'	(b) (4), (b) (6)	01 Apr 2021 19:23:07

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:23:07

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:23:07

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '06 Dec 2020'	(b) (4), (b) (6)	01 Apr 2021 19:23:07

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:23:07

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:13
User entered empty.	System	01 Apr 2021 19:23:07

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:13
User entered empty.	System	01 Apr 2021 19:23:07

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:13
User entered empty.	System	01 Apr 2021 19:23:07

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
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: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:33:54
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 09:33:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
Data point term sent to Coder	System	01 Apr 2021 19:26:10
User entered 'Omeprazole'	(b) (4), (b) (6)	01 Apr 2021 19:25:25

FDA-CBER-2022-1614-0967054

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 19:44:35
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:25:25

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'Gastroesophageal reflux disease,'	(b) (4), (b) (6)	01 Apr 2021 19:25:25

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 19:25:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 19:25:57
User entered '20' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 19:25:57
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 19:25:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 19:25:43
User entered '20'	(b) (4), (b) (6)	01 Apr 2021 19:25:25

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:27:29
DataPoint Un-verified.	Matthew Muniz (b) (4)	14 Apr 2021 15:36:37
User entered 'mg (mg)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	14 Apr 2021 15:36:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	01 Apr 2021 19:25:43
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 19:25:43
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	01 Apr 2021 19:25:25
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Apr 2021 19:25:25

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:13:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
User closed query 'Per CDM: As dose is recorded as 20, kindly consider to update dose unit as appropriate (e.g. mg) and leave this field as blank. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 12:53:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:27:31
Query 'Per CDM: As dose is recorded as 20, kindly consider to update dose unit as appropriate (e.g. mg) and leave this field as blank. Please review and reconcile.' answered with 'UPDATED' (Site from DM).	Matthew Muniz (b) (4)	14 Apr 2021 15:36:51
DataPoint Un-verified.	Matthew Muniz (b) (4)	14 Apr 2021 15:36:37
User entered empty; reason for change Data Entry Error	Matthew Muniz (b) (4)	14 Apr 2021 15:36:37
User opened query 'Per CDM: As dose is recorded as 20, kindly consider to update dose unit as appropriate (e.g. mg) and leave this field as blank. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 08:21:38
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '1 capsule of 20mg'	(b) (4), (b) (6)	01 Apr 2021 19:25:25

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Apr 2021 19:25:25

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:25:25

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Apr 2021 19:25:25

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:25:25

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '01 Dec 2020'	(b) (4), (b) (6)	01 Apr 2021 19:25:25

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:25:25

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:25:25

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '03 Dec 2020'	(b) (4), (b) (6)	01 Apr 2021 19:25:25

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:25:25

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:18
User entered '1'	System	01 Apr 2021 19:25:25

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:18
User entered '1'	System	01 Apr 2021 19:25:25

FDA-CBER-2022-1614-0967070

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:18
User entered '804 (804)'	System	01 Apr 2021 19:25:25

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:13:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 19:29:07
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 19:29:07
Data point term sent to Coder	System	01 Apr 2021 19:28:17
User entered 'Morphine'	(b) (4), (b) (6)	01 Apr 2021 19:28:01

FDA-CBER-2022-1614-0967072

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:13:10

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:28:01

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'pulmonary embolism'	(b) (4), (b) (6)	01 Apr 2021 19:28:01

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:13:10

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '2'	(b) (4), (b) (6)	01 Apr 2021 19:28:01

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:13:10

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'Other (OTHER)'	(b) (4), (b) (6)	01 Apr 2021 19:28:01

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 09 Jun 2021 17:13:10
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '2 mg/ 1 mL'	(b) (4), (b) (6)	01 Apr 2021 19:28:01

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:13:10

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'other (OTHER)'	(b) (4), (b) (6)	01 Apr 2021 19:28:01

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:13:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'every four hours'	(b) (4), (b) (6)	01 Apr 2021 19:28:01

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:13:10

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	01 Apr 2021 19:28:01

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:13:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:28:01

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:13:10

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '29 Nov 2020'	(b) (4), (b) (6)	01 Apr 2021 19:28:01

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:13:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:28:01

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:13:10

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:28:01

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:13:10

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered '30 Nov 2020'	(b) (4), (b) (6)	01 Apr 2021 19:28:01

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:13:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:45:29
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:28:01

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:13:10

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:22
User entered empty.	System	01 Apr 2021 19:28:01

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:22
User entered empty.	System	01 Apr 2021 19:28:01

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:13:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:01:22
User entered empty.	System	01 Apr 2021 19:28:01

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:13:10

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:09
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 17:15:02

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:13:10

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:31
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:04:35

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:13:10

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:31
User entered 'PUNCH BIOPSY'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:04:35

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:31
User entered 'Adverse Event (AE)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:04:35

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:13:10

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:31
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:04:35

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:13:10

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:31
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:07:09

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:13:10

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:31
User entered 'SKIN BIOPSY RIGHT ARM'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:07:09

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:31
User entered 'Adverse Event (AE)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:07:09

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:13:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:31
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:07:09

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:13:10

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:31
User entered '12 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:33:39

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:13:10

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:31
User entered 'SKIN BIOPSY'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:33:39

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:31
User entered 'Adverse Event (AE)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:33:39

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:13:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:31
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:33:39

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:13:10

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered '29 Nov 2020'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:50:08

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:13:10

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered 'Chest CT with contrast'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:50:08

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:50:08

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:13:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:50:08

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:13:10

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered '29 Nov 2020'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:51:09

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:13:10

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered 'Chest X Ray 2 views'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:51:09

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:51:09

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:13:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:51:09

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:13:10

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered '30 Nov 2020'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:58:14

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:13:10

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered 'Echo Doppler'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:58:14

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:58:14

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:13:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:58:14

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:13:10

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered '30 Nov 2020'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:58:36

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:13:10

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered 'EKG'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:58:36

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:58:36

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:13:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:58:36

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:13:10

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:37
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:18:34
User closed query 'Per source the date is 01DEC2020, please clarify.' (Site from CRA).		18 Mar 2021 17:18:26
User closed query 'Per DM CLR: Please review if this Con Proc was done due to AE #5 BILATERAL PULMONARY EMBOLISM (29 Nov 2020-01 Dec 2020). If yes, please review the Date of this procedure as it is out of the expected timeframe of its corresponding AE. Please review and reconcile date of procedure, else, there is no AE condition that matches this procedure. Otherwise, clarify as necessary. ' (Site from DM).		15 Mar 2021 08:23:37
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	12 Mar 2021 22:39:34
User entered '01 Dec 2020' reason for change: Data Entry Error	Matthew Muniz (b) (4)	12 Mar 2021 22:39:34
Query 'Per source the date is 01DEC2020, please clarify.' answered with 'updated' (Site from CRA).	Matthew Muniz (b) (4)	12 Mar 2021 22:39:29
Query 'Per DM CLR: Please review if this Con Proc was done due to AE #5 BILATERAL PULMONARY EMBOLISM (29 Nov 2020-01 Dec 2020). If yes, please review the Date of this procedure as it is out of the expected timeframe of its corresponding AE. Please review and reconcile date of procedure, else, there is no AE condition that matches this procedure. Otherwise, clarify as necessary. ' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	12 Mar 2021 22:39:22
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	12 Mar 2021 22:39:14
User entered '01 Dec 2021' reason for change: Data Entry Error	Matthew Muniz (b) (4)	12 Mar 2021 22:39:14
User opened query 'Per source the date is 01DEC2020, please clarify.' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 20:23:52
User entered '01 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 20:20:39

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:13:10

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this Con Proc was done due to AE #5 BILATERAL PULMONARY EMBOLISM (29 Nov 2020-01 Dec 2020). If yes, please review the Date of this procedure as it is out of the expected timeframe of its corresponding AE. Please review and reconcile date of procedure, else, there is no AE condition that matches this procedure. Otherwise, clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 02:09:36
User entered '1 Jan 2021'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:59:31

FDA-CBER-2022-1614-0967120

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:13:10

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:37
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered 'Venous Doppler Bilateral lower extremeties'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:59:31

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:13:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:37
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:59:31

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:13:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:37
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:33:33
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 18:59:31

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'USA-US066-2020-MRNA-1273-P301000005'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967131

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Howard'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967132

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'schwartz'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967133

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '7265 SHeridan Street SUite 210'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Pembroke Pines'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967135

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'FL'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '33024'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:32:08
User entered 'US'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	02 Apr 2021 12:58:28
User entered '8'	System	22 Mar 2021 17:10:27
User entered '7'	System	08 Mar 2021 14:45:27
User entered '6'	System	19 Feb 2021 15:31:18
User entered '5'	System	11 Dec 2020 14:35:51
User entered '4'	System	09 Dec 2020 19:06:56
User entered '3'	System	25 Nov 2020 17:24:53
User entered '2'	System	18 Nov 2020 14:33:51
User entered '1'	System	13 Nov 2020 13:23:35

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'USA-US066-2020-MRNA-1273-P301000005'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967140

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967147

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Howard'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967148

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'schwartz'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '7265 SHeridan Street SUite 210'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Pembroke Pines'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'FL'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '33024'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:32:08
User entered 'US'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	02 Apr 2021 12:58:28
User entered '8'	System	22 Mar 2021 17:10:27
User entered '7'	System	08 Mar 2021 14:45:27
User entered '6'	System	19 Feb 2021 15:31:18
User entered '5'	System	11 Dec 2020 14:35:51
User entered '4'	System	09 Dec 2020 19:06:56
User entered '3'	System	25 Nov 2020 17:24:53
User entered '2'	System	18 Nov 2020 14:33:51
User entered '1'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:13:10

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
User entered '13/Nov/2020 08:23'	System	13 Nov 2020 13:23:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.		18 Nov 2020 14:32:08
User entered '1'		13 Nov 2020 13:23:35

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'USA-US066-2020-MRNA-1273-P301000005'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967164

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Howard'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967166

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'schwartz'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '7265 SHeridan Street SUite 210'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Pembroke Pines'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967169

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'FL'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '33024'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:32:08
User entered 'US'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	02 Apr 2021 12:58:28
User entered '8'	System	22 Mar 2021 17:10:27
User entered '7'	System	08 Mar 2021 14:45:27
User entered '6'	System	19 Feb 2021 15:31:18
User entered '5'	System	11 Dec 2020 14:35:51
User entered '4'	System	09 Dec 2020 19:06:56
User entered '3'	System	25 Nov 2020 17:24:53
User entered '2'	System	18 Nov 2020 14:33:51
User entered '1'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:13:10

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
User entered '18/Nov/2020 14:33'	System	18 Nov 2020 14:33:51

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:13:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.		25 Nov 2020 17:24:39
User entered '1'		18 Nov 2020 14:33:51

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'USA-US066-2020-MRNA-1273-P301000005'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Howard'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967184

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'schwartz'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967185

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '7265 SHeridan Street SUite 210'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Pembroke Pines'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'FL'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '33024'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:32:08
User entered 'US'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	02 Apr 2021 12:58:28
User entered '8'	System	22 Mar 2021 17:10:27
User entered '7'	System	08 Mar 2021 14:45:27
User entered '6'	System	19 Feb 2021 15:31:18
User entered '5'	System	11 Dec 2020 14:35:51
User entered '4'	System	09 Dec 2020 19:06:56
User entered '3'	System	25 Nov 2020 17:24:53
User entered '2'	System	18 Nov 2020 14:33:51
User entered '1'	System	13 Nov 2020 13:23:35

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
User entered '25/Nov/2020 17:24'	System	25 Nov 2020 17:24:53

FDA-CBER-2022-1614-0967192

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:13:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 19:06:38
DataPoint Verified.		02 Dec 2020 20:00:40
User entered '1'		25 Nov 2020 17:24:53

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'USA-US066-2020-MRNA-1273-P301000005'	System	13 Nov 2020 13:23:15

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Howard'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967202

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'schwartz'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '7265 SHeridan Street SUite 210'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Pembroke Pines'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'FL'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '33024'	System	13 Nov 2020 13:23:15

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:32:08
User entered 'US'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	02 Apr 2021 12:58:28
User entered '8'	System	22 Mar 2021 17:10:27
User entered '7'	System	08 Mar 2021 14:45:27
User entered '6'	System	19 Feb 2021 15:31:18
User entered '5'	System	11 Dec 2020 14:35:51
User entered '4'	System	09 Dec 2020 19:06:56
User entered '3'	System	25 Nov 2020 17:24:53
User entered '2'	System	18 Nov 2020 14:33:51
User entered '1'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:13:10

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:43
User entered '09/Dec/2020 19:06'	System	09 Dec 2020 19:06:56

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:13:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:43
Reviewed for Safety.		11 Dec 2020 14:35:12
User entered '1'		09 Dec 2020 19:06:56

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'USA-US066-2020-MRNA-1273-P301000005'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967213

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967217

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967218

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967219

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Howard'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967220

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'schwartz'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967221

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '7265 SHeridan Street SUite 210'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Pembroke Pines'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'FL'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '33024'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967225

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:32:08
User entered 'US'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	02 Apr 2021 12:58:28
User entered '8'	System	22 Mar 2021 17:10:27
User entered '7'	System	08 Mar 2021 14:45:27
User entered '6'	System	19 Feb 2021 15:31:18
User entered '5'	System	11 Dec 2020 14:35:51
User entered '4'	System	09 Dec 2020 19:06:56
User entered '3'	System	25 Nov 2020 17:24:53
User entered '2'	System	18 Nov 2020 14:33:51
User entered '1'	System	13 Nov 2020 13:23:35

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form (5)
Generated On: 09 Jun 2021 17:13:10
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:43
User entered '11/Dec/2020 14:35'	System	11 Dec 2020 14:35:51

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:13:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:43
Reviewed for Safety.		08 Mar 2021 14:44:54
User entered '1'		11 Dec 2020 14:35:51

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'USA-US066-2020-MRNA-1273-P301000005'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967237

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Howard'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'schwartz'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '7265 SHeridan Street SUite 210'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Pembroke Pines'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'FL'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '33024'	System	13 Nov 2020 13:23:15

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:32:08
User entered 'US'	System	13 Nov 2020 13:23:35

FDA-CBER-2022-1614-0967244

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	02 Apr 2021 12:58:28
User entered '8'	System	22 Mar 2021 17:10:27
User entered '7'	System	08 Mar 2021 14:45:27
User entered '6'	System	19 Feb 2021 15:31:18
User entered '5'	System	11 Dec 2020 14:35:51
User entered '4'	System	09 Dec 2020 19:06:56
User entered '3'	System	25 Nov 2020 17:24:53
User entered '2'	System	18 Nov 2020 14:33:51
User entered '1'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:13:10

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:43
User entered '19/Feb/2021 10:30'	System	19 Feb 2021 15:31:18

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:13:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:43
Reviewed for Safety.		08 Mar 2021 14:44:54
User entered '1'		19 Feb 2021 15:31:18

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'USA-US066-2020-MRNA-1273-P301000005'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967253

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967255

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Howard'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967256

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'schwartz'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967257

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '7265 SHeridan Street SUite 210'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Pembroke Pines'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'FL'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '33024'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967261

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:32:08
User entered 'US'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	02 Apr 2021 12:58:28
User entered '8'	System	22 Mar 2021 17:10:27
User entered '7'	System	08 Mar 2021 14:45:27
User entered '6'	System	19 Feb 2021 15:31:18
User entered '5'	System	11 Dec 2020 14:35:51
User entered '4'	System	09 Dec 2020 19:06:56
User entered '3'	System	25 Nov 2020 17:24:53
User entered '2'	System	18 Nov 2020 14:33:51
User entered '1'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:13:10

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:43
User entered '08/Mar/2021 09:45'	System	08 Mar 2021 14:45:27

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:13:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:43
User entered '1'	(b) (4), (b) (6)	08 Mar 2021 14:45:27

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'USA-US066-2020-MRNA-1273-P301000005'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967268

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Howard'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967274

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'schwartz'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '7265 SHeridan Street SUite 210'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967276

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Pembroke Pines'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'FL'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '33024'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967279

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:32:08
User entered 'US'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	02 Apr 2021 12:58:28
User entered '8'	System	22 Mar 2021 17:10:27
User entered '7'	System	08 Mar 2021 14:45:27
User entered '6'	System	19 Feb 2021 15:31:18
User entered '5'	System	11 Dec 2020 14:35:51
User entered '4'	System	09 Dec 2020 19:06:56
User entered '3'	System	25 Nov 2020 17:24:53
User entered '2'	System	18 Nov 2020 14:33:51
User entered '1'	System	13 Nov 2020 13:23:35

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form (8)
Generated On: 09 Jun 2021 17:13:10
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:43
User entered '22/Mar/2021 13:10'	System	22 Mar 2021 17:10:27

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:13:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:43
User entered '1'	(b) (4), (b) (6)	22 Mar 2021 17:10:27

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'USA-US066-2020-MRNA-1273-P301000005'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967291

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Howard'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967292

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'schwartz'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '7265 SHeridan Street SUite 210'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Pembroke Pines'	System	13 Nov 2020 13:23:15

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'FL'	System	13 Nov 2020 13:23:15

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '33024'	System	13 Nov 2020 13:23:15

FDA-CBER-2022-1614-0967297

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:00:40
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:32:08
User entered 'US'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	02 Apr 2021 12:58:28
User entered '8'	System	22 Mar 2021 17:10:27
User entered '7'	System	08 Mar 2021 14:45:27
User entered '6'	System	19 Feb 2021 15:31:18
User entered '5'	System	11 Dec 2020 14:35:51
User entered '4'	System	09 Dec 2020 19:06:56
User entered '3'	System	25 Nov 2020 17:24:53
User entered '2'	System	18 Nov 2020 14:33:51
User entered '1'	System	13 Nov 2020 13:23:35

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000005
Form: Safety Report Form (9)
Generated On: 09 Jun 2021 17:13:10
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:43
User entered '02/Apr/2021 05:58'	System	02 Apr 2021 12:58:28

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:13:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:43
User entered '1'	(b) (4), (b) (6)	02 Apr 2021 12:58:28

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

SAEID

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'USA-US066-2020-MRNA-1273-P301000009'	System	09 Dec 2020 17:51:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 02:06:05
Un-reviewed for Safety.	System	09 Dec 2020 20:01:21
User entered 'Yes (Y)'	System	09 Dec 2020 20:01:21
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

FDA-CBER-2022-1614-0967303

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 02:06:05
Un-reviewed for Safety.	System	09 Dec 2020 20:01:21
User entered 'Yes (Y)'	System	09 Dec 2020 20:01:21
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

FDA-CBER-2022-1614-0967308

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'Howard'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'schwartz'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered '7265 SHeridan Street SUite 210'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'Pembroke Pines'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'FL'	System	09 Dec 2020 17:51:41

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered '33024'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 02:06:05
User entered 'US'	System	09 Dec 2020 17:52:20

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '3'	System	19 Feb 2021 19:15:25
User entered '2'	System	10 Dec 2020 02:06:26
User entered '1'	System	09 Dec 2020 17:52:20

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'USA-US066-2020-MRNA-1273-P301000009'	System	09 Dec 2020 17:51:41

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 02:06:05
Un-reviewed for Safety.	System	09 Dec 2020 20:01:21
User entered 'Yes (Y)'	System	09 Dec 2020 20:01:21
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 02:06:05
Un-reviewed for Safety.	System	09 Dec 2020 20:01:21
User entered 'Yes (Y)'	System	09 Dec 2020 20:01:21
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'Howard'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'schwartz'	System	09 Dec 2020 17:51:41

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered '7265 SHeridan Street SUite 210'	System	09 Dec 2020 17:51:41

FDA-CBER-2022-1614-0967328

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'Pembroke Pines'	System	09 Dec 2020 17:51:41

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'FL'	System	09 Dec 2020 17:51:41

FDA-CBER-2022-1614-0967330

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered '33024'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 02:06:05
User entered 'US'	System	09 Dec 2020 17:52:20

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '3'	System	19 Feb 2021 19:15:25
User entered '2'	System	10 Dec 2020 02:06:26
User entered '1'	System	09 Dec 2020 17:52:20

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:13:10

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
User entered '09/Dec/2020 17:52'	System	09 Dec 2020 17:52:20

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:13:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 02:06:05
User entered '1'	(b) (4), (b) (6)	09 Dec 2020 17:52:20

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'USA-US066-2020-MRNA-1273-P301000009'	System	09 Dec 2020 17:51:41

FDA-CBER-2022-1614-0967336

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 02:06:05
Un-reviewed for Safety.	System	09 Dec 2020 20:01:21
User entered 'Yes (Y)'	System	09 Dec 2020 20:01:21
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 02:06:05
Un-reviewed for Safety.	System	09 Dec 2020 20:01:21
User entered 'Yes (Y)'	System	09 Dec 2020 20:01:21
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'Howard'	System	09 Dec 2020 17:51:41

FDA-CBER-2022-1614-0967344

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'schwartz'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered '7265 SHeridan Street SUite 210'	System	09 Dec 2020 17:51:41

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'Pembroke Pines'	System	09 Dec 2020 17:51:41

FDA-CBER-2022-1614-0967347

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'FL'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered '33024'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 02:06:05
User entered 'US'	System	09 Dec 2020 17:52:20

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '3'	System	19 Feb 2021 19:15:25
User entered '2'	System	10 Dec 2020 02:06:26
User entered '1'	System	09 Dec 2020 17:52:20

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:13:10

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
User entered '10/Dec/2020 02:06'	System	10 Dec 2020 02:06:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 19:15:39
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
User entered '1'	(b) (4), (b) (6)	10 Dec 2020 02:06:26

FDA-CBER-2022-1614-0967353

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'USA-US066-2020-MRNA-1273-P301000009'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 02:06:05
Un-reviewed for Safety.	System	09 Dec 2020 20:01:21
User entered 'Yes (Y)'	System	09 Dec 2020 20:01:21
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 02:06:05
Un-reviewed for Safety.	System	09 Dec 2020 20:01:21
User entered 'Yes (Y)'	System	09 Dec 2020 20:01:21
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

FDA-CBER-2022-1614-0967359

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'No (N)'	System	09 Dec 2020 17:51:41

FDA-CBER-2022-1614-0967361

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'Howard'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'schwartz'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered '7265 SHeridan Street SUite 210'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'Pembroke Pines'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered 'FL'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:52:07
User entered '33024'	System	09 Dec 2020 17:51:41

US3352299
Folder: SAE USA-US066-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 09 Jun 2021 17:13:10
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:37:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 02:06:05
User entered 'US'	System	09 Dec 2020 17:52:20

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:10

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '3'	System	19 Feb 2021 19:15:25
User entered '2'	System	10 Dec 2020 02:06:26
User entered '1'	System	09 Dec 2020 17:52:20

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:13:10

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:54
User entered '19/Feb/2021 14:15'	System	19 Feb 2021 19:15:25

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:13:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:26:23
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 19:15:39
User entered '1'	(b) (4), (b) (6)	19 Feb 2021 19:15:25