US3252119 (Prod: Centex Studies Inc)

US3252119
Form: Participant Creation
Data signed: (b) (4) **05 Mar 2021 20:13:46**
Generated On: 09 Jun 2021 16:17:00

Participant ID   US3252119

mRNA-1273-P301 Completion Guidelines

Folder: Screening
Form: Visit Date
Data signed: (b) (4) **04 Mar 2021 23:45:37**
Generated On: 09 Jun 2021 16:17:00

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	SCRN

US3252119

Folder: Screening

Form: Demographics

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	57
Age Units	YEARS
Age (Derived)	57
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

Date of Informed Consent *(dd MMM yyyy)*	11 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020

Protocol Version

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

Was participant enrolled in the study?

- Yes ●
- No ○

If No, indicate reason for screen fail

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

If reason for screen fail is Other, specify _____

Was this participant screened previously?

- Yes ○
- No ●

If Yes, previous participant number _____

Enrollment Trigger	1

Did the participant meet all eligibility criteria?   Yes ⬤

No ◯

Were any significant conditions reported?　　　　　　　　　　Yes ●

No ○

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

Condition	TYPE II DIABETES
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3252119

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 04 Mar 2021 23:45:37

Generated On: 09 Jun 2021 16:17:00

Condition	LEFT FOOT INFECTION
Start date (dd MMM yyyy)	UN APR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3252119

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 04 Mar 2021 23:45:37

Generated On: 09 Jun 2021 16:17:00

Condition	REMOVAL OF FIFTH LEFT TOE
Start date (dd MMM yyyy)	UN NOV 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ⭕
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN NOV 2016
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2016
Start Year (derived)	2016
Stop Month and Year (derived)	NOV 2016
Stop Year (derived)	2016

US3252119

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

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

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

Condition	LEFT FOOT INFECTION
Start date (dd MMM yyyy)	UN NOV 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN NOV 2016
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2016
Start Year (derived)	2016
Stop Month and Year (derived)	NOV 2016
Stop Year (derived)	2016

US3252119

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 04 Mar 2021 23:45:37

Generated On: 09 Jun 2021 16:17:00

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	11 AUG 2020
Time of assessment *(00:00-23:59)*	11:32 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 11:32
Height *(xxx.x)*	71.3 in
Weight *(xxx.x)*	313 lb
BMI *(xxx.x)*	43.37856 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)	

US3252119

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

Was the physical examination performed?	Yes ⬤
	No ◯

Date of examination *(dd MMM yyyy)*	11 AUG 2020

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

US3252119

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

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   GM ▓▓▓▓ (b) (6)

Location and Living Circumstances Risk (check all that apply)

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

US3252119

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 04 Mar 2021 23:45:37

Generated On: 09 Jun 2021 16:17:00

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	

US3252119
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **04 Mar 2021 23:45:37**
Generated On: 09 Jun 2021 16:17:00

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT1

US3252119
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) 04 Mar 2021 23:45:37
Generated On: 09 Jun 2021 16:17:00

What was the date of randomization? *(dd MMM yyyy)*	11 AUG 2020
What was the participant's randomization number?	143657

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	⬤

US3252119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

Height	ND - Not Done
Weight	ND - Not Done

US3252119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

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)*	11 AUG 2020
Time of assessment *(00:00-23:59)*	11:32 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 11:32
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	90 mmHg
Diastolic Blood Pressure units	MMHG

US3252119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

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)*	11 AUG 2020
Time of assessment *(00:00-23:59)*	13:12 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 13:12
Temperature *(xxx.x)*	97.6 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	77 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	84 mmHg
Diastolic Blood Pressure units	MMHG

US3252119

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

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)*	11 AUG 2020
What was the treatment time? *(00:00-23:59)*	12:25 (24 HR)
Treatment Date and Time (derived)	11 AUG 2020 12:25
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

US3252119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	11 AUG 2020
Collection time *(00:00-23:59)*	12:00 (24 HR)
Collection date and time (derived)	11 AUG 2020 12:00

US3252119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

Collection date *(dd MMM yyyy)* 11 AUG 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:49	11 AUG 2020 11:49
Nasopharyngeal Swab 2	No		

US3252119
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **04 Mar 2021 23:45:37**
Generated On: 09 Jun 2021 16:17:00

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**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	11 AUG 2020 13:02
PC Open Date & Time	11 AUG 2020 12:45
PC Close Date & Time	11 AUG 2020 15:15

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:17:00

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**	

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

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

To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	11 AUG 2020 16:10
PC Close Date & Time	12 AUG 2020 11:59

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:17:00

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ●
	No ○
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes ○
	No ●

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

PC Time Stamp	13 AUG 2020 09:37
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-0713598

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:17:00

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**	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	14 AUG 2020 07:55
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:17:00

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**	96.6 °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	15 AUG 2020 10:30
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.9 °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	16 AUG 2020 06:03
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3252119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:00

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**	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	16 AUG 2020 21:42
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

TIMEPOINT	**DAY 7**

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.1 °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	18 AUG 2020 07:33
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

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	11 AUG 2020 13:02
PC Open Date & Time	11 AUG 2020 12:45
PC Close Date & Time	11 AUG 2020 15:15

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:17:00

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 ◯

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

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

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

Yes ◯
No ◯

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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	
PC Open Date & Time	11 AUG 2020 16:10
PC Close Date & Time	12 AUG 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	13 AUG 2020 09:37
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:17:00

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	14 AUG 2020 07:55
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:17:00

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	15 AUG 2020 10:30
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:00

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	16 AUG 2020 06:03
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:00

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	16 AUG 2020 21:42
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:00

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	18 AUG 2020 07:34
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:17:00

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 ○

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

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

PC Time stamp	11 AUG 2020 13:03
PC Open Date & Time	11 AUG 2020 12:45
PC Close Date & Time	11 AUG 2020 15:15

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:17:00

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	
PC Open Date & Time	11 AUG 2020 16:10
PC Close Date & Time	12 AUG 2020 11:59

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00

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	13 AUG 2020 09:38
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

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	14 AUG 2020 07:56
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

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	15 AUG 2020 10:31
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:00

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	16 AUG 2020 06:04
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:17:00

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 ●

	Yes ◯
PC Time stamp	16 AUG 2020 21:43
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00

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	18 AUG 2020 07:34
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3252119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	19 AUG 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3252119

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3252119
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **04 Mar 2021 23:45:37**
Generated On: 09 Jun 2021 16:17:00

Was Contact Attempted?	Yes ⬤
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*   25 AUG 2020

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

Comments

If Contact Not Made, please provide Comments   _____

US3252119
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **04 Mar 2021 23:45:37**
Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?   Yes ⬤

                                                                 No ◯

Continuing Flag   1

US3252119
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **04 Mar 2021 23:45:37**
Generated On: 09 Jun 2021 16:17:00

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 01 SEP 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3252119

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3252119
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **04 Mar 2021 23:45:38**
Generated On: 09 Jun 2021 16:17:00

| Was this visit performed? | Yes ● |
| | No ○ |

| Visit date (dd MMM yyyy) | 8 SEP 2020 |

| Was visit performed at the participant's home or at the clinic? | Home ○ |
| | Clinic ● |

| Folder OID | VISIT2 |

US3252119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **04 Mar 2021 23:45:38**

Generated On: 09 Jun 2021 16:17:00

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	8 SEP 2020
Time of assessment *(00:00-23:59)*	13:32 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 13:32
Temperature *(xxx.x)*	97.8 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	87 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

Timepoint	Pre-Dose ⦿
	Post-Dose ●
Were vital signs assessed?	Yes ●
	No ⦿
Date of assessment *(dd MMM yyyy)*	8 SEP 2020
Time of assessment *(00:00-23:59)*	15:18 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 15:18
Temperature *(xxx.x)*	97.8 F
Route of measurement	Oral ●
	Axillary ⦿
	Other ⦿
If Other, specify	
Pulse *(xxx)*	82 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	72 mmHg
Diastolic Blood Pressure units	MMHG

US3252119
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **04 Mar 2021 23:45:38**
Generated On: 09 Jun 2021 16:17:00

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)*	8 SEP 2020
What was the treatment time? *(00:00-23:59)*	14:41 (24 HR)
Treatment Date and Time (derived)	8 SEP 2020 14:41
Which arm was used to give treatment?	Left Arm ⬤
	Right Arm ◯
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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US3252119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **04 Mar 2021 23:45:38**

Generated On: 09 Jun 2021 16:17:00

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	8 SEP 2020
Collection time *(00:00-23:59)*	14:15 (24 HR)
Collection date and time (derived)	8 SEP 2020 14:15

US3252119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **04 Mar 2021 23:45:38**

Generated On: 09 Jun 2021 16:17:00

Collection date *(dd MMM yyyy)*   8 SEP 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:41	8 SEP 2020 13:41
Nasopharyngeal Swab 2	No		

Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **04 Mar 2021 23:45:38**
Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?   Yes ●

                                                                     No ○

Continuing Flag   1

US3252119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	08 SEP 2020 15:21
PC Open Date & Time	08 SEP 2020 15:01
PC Close Date & Time	08 SEP 2020 17:31

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**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	08 SEP 2020 20:11
PC Open Date & Time	08 SEP 2020 18:26
PC Close Date & Time	09 SEP 2020 11:59

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:17:00

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.3 °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	09 SEP 2020 21:23
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:17:00

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**	96.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	10 SEP 2020 22:51
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:17:00

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**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯ No ◯
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

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**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯ No ◯
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:17:00

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	96.9 °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	14 SEP 2020 07:12
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:17:00

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**	96.7 °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	14 SEP 2020 20:34
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	08 SEP 2020 15:22
PC Open Date & Time	08 SEP 2020 15:01
PC Close Date & Time	08 SEP 2020 17:31

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	08 SEP 2020 20:11
PC Open Date & Time	08 SEP 2020 18:26
PC Close Date & Time	09 SEP 2020 11:59

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:00

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	09 SEP 2020 21:24
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:17:00

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	10 SEP 2020 22:51
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:17:00

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 ◯

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

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

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

- Yes ◯
- No ◯

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided. _____

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	_____
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:17:00

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 ◯

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

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

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

- Yes ◯
- No ◯

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided. _____

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	_____
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 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	14 SEP 2020 07:12
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 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	14 SEP 2020 20:34
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:17:00

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 ○

US3252119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

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

PC Time stamp	08 SEP 2020 15:22
PC Open Date & Time	08 SEP 2020 15:01
PC Close Date & Time	08 SEP 2020 17:31

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:17:00

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	○

US3252119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:00

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

PC Time stamp	08 SEP 2020 20:12
PC Open Date & Time	08 SEP 2020 18:26
PC Close Date & Time	09 SEP 2020 11:59

US3252119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:00

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	09 SEP 2020 21:24
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:17:00

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 ⬤

FDA-CBER-2022-1614-0713664

	Yes ◯
PC Time stamp	10 SEP 2020 22:52
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

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 ◯

FDA-CBER-2022-1614-0713666

Yes ⬭

PC Time stamp	
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 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	
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:17:00

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 ●

	Yes ○
PC Time stamp	14 SEP 2020 07:13
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00

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	14 SEP 2020 20:35
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3252119
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **04 Mar 2021 23:45:37**
Generated On: 09 Jun 2021 16:17:00

| 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

US3252119

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?　　　　　　　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　　　1

US3252119
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **04 Mar 2021 23:45:37**
Generated On: 09 Jun 2021 16:17:00

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 24 SEP 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3252119

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **04 Mar 2021 23:45:37**

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?   Yes ⬤

                                                            No ◯

Continuing Flag   1

US3252119
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **04 Mar 2021 23:45:37**
Generated On: 09 Jun 2021 16:17:00

Was Contact Attempted?   Yes ●

                                                                      No ○

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

Please select one status for the follow-up contact   Contact Made ●

                                                        Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3252119
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **04 Mar 2021 23:45:37**
Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?   Yes ●

                                                                                    No ○

Continuing Flag   1

| Was this visit performed? | Yes ● |
| | No ○ |

Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

| Folder OID | VISIT3 |

US3252119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **04 Mar 2021 23:45:38**

Generated On: 09 Jun 2021 16:17:00

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	7 OCT 2020
Time of assessment *(00:00-23:59)*	9:37 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 9:37
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	94 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252119

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **04 Mar 2021 23:45:38**

Generated On: 09 Jun 2021 16:17:00

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) **04 Mar 2021 23:45:38**
Generated On: 09 Jun 2021 16:17:00

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	7 OCT 2020
Collection time *(00:00-23:59)*	9:45 (24 HR)
Collection date and time (derived)	7 OCT 2020 9:45

US3252119

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **04 Mar 2021 23:45:38**

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?   Yes ●

                                                                   No ○

Continuing Flag   1

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬤
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 OCT 2020 08:31:06
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3252119
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

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	20 OCT 2020 11:21:10
Patient Cloud Open Date & Time	18 OCT 2020 00:01
Patient Cloud Close Date & Time	22 OCT 2020 23:59

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ○
Have 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	25 OCT 2020 09:46:02
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

FDA-CBER-2022-1614-0713687

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 NOV 2020 05:18:04
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 09:23:33
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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	21 NOV 2020 21:46:55
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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	29 NOV 2020 18:16:50
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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	04 DEC 2020 14:12:36
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 16:13:53
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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	19 DEC 2020 17:19:08
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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	25 DEC 2020 14:12:22
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT DAY 145

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

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

Fever (Temperature $\geq$ 100.4°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-2022-1614-0713696

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

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	08 JAN 2021 16:52:50
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 159

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

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

Fever (Temperature ≥ 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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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	22 JAN 2021 22:39:36
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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	28 JAN 2021 16:25:07
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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	06 FEB 2021 22:16:00
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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	11 FEB 2021 17:44:04
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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	20 FEB 2021 09:04:09
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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	25 FEB 2021 17:27:38
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

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	05 MAR 2021 14:48:26
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 MAR 2021 10:55:39
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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	20 MAR 2021 21:30:07
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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	27 MAR 2021 19:29:20
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT **DAY 236**

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT	DAY 243

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

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

Fever (Temperature $\geq$ 100.4°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 ⭘

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 APR 2021 08:57:37
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 APR 2021 16:13:29
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚫
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚫ Yes ⚪
Have 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 MAY 2021 12:07:13
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

FDA-CBER-2022-1614-0713717

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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):

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 ⃝

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT DAY 278

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

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

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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ≥ 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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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-2022-1614-0713724

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 299

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

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

Fever (Temperature $\geq$ 100.4°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 ⭕

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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-2022-1614-0713728

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT DAY 313

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 320

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ⭕

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 334

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

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

Fever (Temperature $\geq$ 100.4°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 ⬭

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 341

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

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

Fever (Temperature ≥ 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-2022-1614-0713738

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ⬭

FDA-CBER-2022-1614-0713740

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 355

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

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

Fever (Temperature $\geq$ 100.4°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-2022-1614-0713742

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

Have you been exposed to someone with known SARS-CoV-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	⃝

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-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-2022-1614-0713746

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 376

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT DAY 383

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

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

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

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ⬭

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 397

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

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

Fever (Temperature ≥ 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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

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

Fever (Temperature $\geq$ 100.4°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-2022-1614-0713756

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ⭕

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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):

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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 432

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

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

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

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

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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):

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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ≥ 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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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):

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-2022-1614-0713774

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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):

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 ⃝

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT　　　　　　　　　　　　　　　　　　　　　　　　DAY 481

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

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

Fever (Temperature $\geq$ 100.4°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-2022-1614-0713778

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ⭕

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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-2022-1614-0713784

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 509

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 516

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

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

Fever (Temperature $\geq$ 100.4°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-2022-1614-0713788

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

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):

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-2022-1614-0713790

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT　　　　　　　　　　　　　　　　　　　　　**DAY 530**

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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):

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-2022-1614-0713794

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT　　　　　　　　　　　　　　　　　　　　**DAY 544**

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT DAY 558

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

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

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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 565

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

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

Fever (Temperature ≥ 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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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):

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-2022-1614-0713804

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 579

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 586

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT **DAY 593**

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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):

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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ≥ 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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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):

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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 628

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

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

Fever (Temperature ≥ 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 ◯

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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-2022-1614-0713822

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 642

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

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

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

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ≥ 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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 670

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 677

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

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

Fever (Temperature $\geq$ 100.4°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 ⭘

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT DAY 684

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

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

Fever (Temperature $\geq$ 100.4°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-2022-1614-0713836

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT DAY 691

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

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

Fever (Temperature $\geq$ 100.4°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-2022-1614-0713838

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ◯

FDA-CBER-2022-1614-0713840

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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):

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-2022-1614-0713842

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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):

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 ⭕

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT **DAY 733**

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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-2022-1614-0713854

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

TIMEPOINT DAY 761

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ≥ 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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT DAY 775

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 ≥ 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-2022-1614-0713864

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT   DAY 789

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-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 ⬭

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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

US3252119

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:17:00

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 22:25:36

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	3 NOV 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3252119
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 20:13:47**
Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3252119
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 20:13:47**
Generated On: 09 Jun 2021 16:17:00

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 7 DEC 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3252119

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **05 Mar 2021 20:13:47**

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

US3252119
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 20:13:47**
Generated On: 09 Jun 2021 16:17:00

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	6 JAN 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3252119

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **05 Mar 2021 20:13:47**

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3252119
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 20:13:47**
Generated On: 09 Jun 2021 16:17:00

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	8 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3252119

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **05 Mar 2021 20:13:47**

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3252119
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **05 Apr 2021 19:48:15**
Generated On: 09 Jun 2021 16:17:00

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	19 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	VISIT4

US3252119
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **05 Apr 2021 19:48:16**
Generated On: 09 Jun 2021 16:17:00

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)   _____

US3252119

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) **05 Apr 2021 19:48:15**

Generated On: 09 Jun 2021 16:17:00

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 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **05 Apr 2021 19:48:15**

Generated On: 09 Jun 2021 16:17:00

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	19 MAR 2021
Collection time *(00:00-23:59)*	09:25 (24 HR)
Collection date and time (derived)	19 MAR 2021 09:25

US3252119
Folder: Visit 4 Day 209 (1)
Form: Continuing
Data signed: (b) (4) **05 Apr 2021 19:48:15**
Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3252119
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00

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 _____

US3252119
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:17:00

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

Continuing Flag   _____

US3252119
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 16:17:00

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 ◯

US3252119
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Generated On: 09 Jun 2021 16:17:00

Generate Next COVID-19 Assessment	Yes ◯
	No ◯

US3252119

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

Form: Visit Date

Data signed: (b) (4) **05 Mar 2021 20:13:47**

Generated On: 09 Jun 2021 16:17:00

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	22 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	UNBLND_DECIDE

US3252119

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 19:48:15

Generated On: 09 Jun 2021 16:17:00

Date of updated informed consent *(dd MMM yyyy)*	22 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)*	22 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	1
Continuing with mRNA-1273	1

US3252119
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Data signed: (b) (4) **05 Mar 2021 20:13:47**
Generated On: 09 Jun 2021 16:17:00

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

US3252119

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **05 Mar 2021 20:13:47**

Generated On: 09 Jun 2021 16:17:00

Height	ND - Not Done
Weight	ND - Not Done
BMI *(xxx.x)*	
Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	22 JAN 2021
Time of assessment *(00:00-23:59)*	09:21 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 09:21
Temperature *(xxx.x)*	98.5 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	90 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

US3252119

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **05 Mar 2021 20:13:47**

Generated On: 09 Jun 2021 16:17:00

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	22 JAN 2021
Time of assessment *(00:00-23:59)*	10:12 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 10:12
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	86 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG

US3252119

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

Form: Physical Examination

Data signed: (b) (4) **05 Mar 2021 20:13:47**

Generated On: 09 Jun 2021 16:17:00

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? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	22 JAN 2021
What was the treatment time? *(00:00-23:59)*	09:39 (24 HR)
Treatment Date and Time (derived)	22 JAN 2021 09:39

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

US3252119

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

Form: Immunogenicity Assessment

Data signed: (b) (4) **05 Mar 2021 20:13:47**

Generated On: 09 Jun 2021 16:17:00

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	22 JAN 2021
Collection time *(00:00-23:59)*	09:20 (24 HR)
Collection date and time (derived)	22 JAN 2021 09:20

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **05 Mar 2021 20:13:47**

Generated On: 09 Jun 2021 16:17:00

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	22 JAN 2021
Collection time *(00:00 - 23:59)*	09:20
Collection Date and Time (derived)	22 JAN 2021 09:20

US3252119

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

Form: Continuing

Data signed: (b) (4) **05 Mar 2021 20:13:47**

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

US3252119
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Data signed: (b) (4) 05 Mar 2021 20:13:47
Generated On: 09 Jun 2021 16:17:00

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

Date of Contact or Contact Attempt *(dd MMM yyyy)* — 29 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3252119

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) **05 Mar 2021 20:13:47**

Generated On: 09 Jun 2021 16:17:00

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

Continuing Flag	1
OLD29 Placebo Flag	1

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	19 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	OLD29

US3252119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **05 Mar 2021 20:13:47**

Generated On: 09 Jun 2021 16:17:00

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	19 FEB 2021
Time of assessment *(00:00-23:59)*	16:26 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 16:26
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	99 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 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

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	19 FEB 2021
Time of assessment *(00:00-23:59)*	17:35 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 17:35
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	128 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

US3252119
Folder: OL-D29 (1)
Form: Physical Examination
Data signed: (b) (4) **05 Mar 2021 20:13:47**
Generated On: 09 Jun 2021 16:17:00

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? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	19 FEB 2021
What was the treatment time? *(00:00-23:59)*	16:57 (24 HR)
Treatment Date and Time (derived)	19 FEB 2021 16:57
Which arm was used to give treatment?	Left Arm ●
	Right Arm ○
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3252119
Folder: OL-D29 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 20:13:47**
Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3252119
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 20:13:47**
Generated On: 09 Jun 2021 16:17:00

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

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

Comments

If Contact Not Made, please provide Comments

US3252119
Folder: Safety Call OL-D36 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 20:13:47**
Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?   Yes ●

                                                                        No ○

Continuing Flag   1

US3252119
Folder: OL-D57 (1)
Form: Visit Date
Data signed: (b) (4) **05 Apr 2021 19:48:15**
Generated On: 09 Jun 2021 16:17:00

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	19 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	OLD57

US3252119
Folder: OL-D57 (1)
Form: Vital Signs
Data signed: (b) (4) **05 Apr 2021 19:48:15**
Generated On: 09 Jun 2021 16:17:00

Were vital signs assessed?	Yes ●
	No ◯
Date of assessment *(dd MMM yyyy)*	19 MAR 2021
Time of assessment *(00:00-23:59)*	09:11 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 09:11
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ●
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	87 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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 the sample collected?   Yes ◯

                                                                   No ⬤

Collection date *(dd MMM yyyy)*

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

Collection date and time (derived)

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **05 Mar 2021 20:13:46**

Generated On: 09 Jun 2021 16:17:00

Did the participant experience any adverse events?   Yes ●

No ◯

If Yes, enter details on the Adverse Events form.

AEID	USA-US108-2020-MRNA-1273-P30 1000006
Adverse event	MYOCARDIAL INFARCTION

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)* 14 OCT 2020

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

AE start date and time (derived)

Ongoing? Yes ○ No ●

  If not Ongoing, end date *(dd MMM yyyy)* 20 OCT 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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	14 OCT 2020
Hospital Discharge Date *(dd MMM yyyy)*	20 OCT 2020

  Admitted to ICU? Yes ● No ○ Unknown ○

FDA-CBER-2022-1614-0713913

Number of Days in ICU	3
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product

- None ○
- Dose Delayed ○
- Investigational Product Withdrawn ○
- Not Applicable ●

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	True

Outcome

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

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

Narrative

	PATIENT CALLED US TO NOTIFY US THAT HE SUFFERED A MYOCARDIAL INFARCTION, TREATED WITH MEDICATION AND A REVASCULARIZATION PROCEDURE, WE WILL UPDATE THE CHART WHEN WE RECEIVE THE HOSPITAL DISCHARGE DOCUMENTATION.
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)	1

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **05 Mar 2021 20:13:46**

Generated On: 09 Jun 2021 16:17:00

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) **05 Apr 2021 19:48:11**

Generated On: 09 Jun 2021 16:17:00

Name of Medication	VICTOZA INJECTION PEN

Prophylaxis	
Yes	○
No	●

Indication	TYPE II DIABETES
Dose per administration	1.8

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	○

Folder: Concomitant Medication and Vaccination (1)
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Data signed: (b) (4) **05 Apr 2021 19:48:11**
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	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 2016
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯

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

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

Name of Medication	LANTUS

Prophylaxis	Yes ⭕
	No ⚫

Indication	TYPE II DIABETES

Dose per administration	100

Dose unit	mg ⭕
	ug ⭕
	mL ⭕
	g ⭕
	IU ⭕
	tablet ⭕
	capsule ⭕
	puff ⭕
	Other ⚫

If dose unit is Other, specify	UNITS/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)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) **05 Apr 2021 19:48:11**

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Name of Medication	SIMVASTATIN
Prophylaxis	Yes ○
	No ●
Indication	HYPERLIPIDEMIA
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 ○

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **05 Apr 2021 19:48:11**
Generated On: 09 Jun 2021 16:17:00

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 2016
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) **05 Apr 2021 19:48:11**

Generated On: 09 Jun 2021 16:17:00

Name of Medication	LISINOPRIL

Prophylaxis

Yes ⚪

No ⚫

Indication	HYPERTENSION
Dose per administration	2.5

Dose unit

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

If dose unit is Other, specify _____

Frequency

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

If frequency is Other, specify _____

Route of administration

Oral ⚫
Topical ⚪
Subcutaneous ⚪
Transdermal ⚪
Intraocular ⚪

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EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) 05 Apr 2021 19:48:11
Generated On: 09 Jun 2021 16:17:00

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 2016
Start date completely unknown	False
Ongoing?	Yes ●
	No ○
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **05 Apr 2021 19:48:11**

Generated On: 09 Jun 2021 16:17:00

Name of Medication	METRONIDAZOL

Prophylaxis	
Yes	⚪
No	⬤

Indication	LEFT FOOT INFECTION
Dose per administration	500

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration	
Oral	⬤
Topical	⚪
Subcutaneous	⚪
Transdermal	⚪
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)*	UN APR 2020
Start date completely unknown	False
Ongoing?	Yes ⬭
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	11 AUG 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 (6)

Data signed: (b) (4) **05 Apr 2021 19:48:11**

Generated On: 09 Jun 2021 16:17:00

Name of Medication	CEDINIR
Prophylaxis	Yes ◯
	No ⬤
Indication	ANTIBIOTICS FOR FOOT INFECTION
Dose per administration	300
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 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	15 SEP 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 (7)

Data signed: (b) (4) **05 Apr 2021 19:48:11**

Generated On: 09 Jun 2021 16:17:00

Name of Medication	ASPIRIN
Prophylaxis	Yes ●
	No ○
Indication	GENERAL HEALTH
Dose per administration	81

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)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **05 Apr 2021 19:48:11**
Generated On: 09 Jun 2021 16:17:00

	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)*	12 JUN 2019
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **05 Apr 2021 19:48:11**

Generated On: 09 Jun 2021 16:17:00

Name of Medication	ATORVASTATIN CALCIUM

Prophylaxis

Yes ◯
No ⬤

Indication	HYPERLIPIDEMIA
Dose per administration	40

Dose unit

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

If dose unit is Other, specify

Frequency

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

If frequency is Other, specify

Route of administration

Oral ⬤
Topical ◯
Subcutaneous ◯
Transdermal ◯
Intraocular ◯

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **05 Apr 2021 19:48:11**

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	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)*	15 OCT 2019
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	20 OCT 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 (9)

Data signed: (b) (4) **05 Apr 2021 19:48:11**

Generated On: 09 Jun 2021 16:17:00

Name of Medication	FAMOTIDINE

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 ◯

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) 05 Apr 2021 19:48:11
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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)*	15 OCT 2019
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	20 OCT 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 (10)

Data signed: (b) (4) **05 Apr 2021 19:48:11**

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Name of Medication	ZOLPIDEM TARTRATE

Prophylaxis

Yes ●

No ○

Indication	NAUSEA

Dose per administration	5

Dose unit

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

If dose unit is Other, specify

Frequency

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

If frequency is Other, specify

Route of administration

Oral ●
Topical ○
Subcutaneous ○
Transdermal ○
Intraocular ○

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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)*	15 OCT 2019
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	20 OCT 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	INSULIN HUMAN REGULAR
Prophylaxis	Yes ◯
	No ⬤
Indication	TYPE 2 DIABETES
Dose per administration	SLIDING SCALE
Dose unit	mg ◯
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ⬤
If dose unit is Other, specify	SLIDING SCALE
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 ◯

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Data signed: (b) (4) 05 Apr 2021 19:48:11
Generated On: 09 Jun 2021 16:17:00

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)*	15 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	20 OCT 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 ◯

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) **05 Apr 2021 19:48:11**

Generated On: 09 Jun 2021 16:17:00

Name of Medication	MUPIROCIN
Prophylaxis	Yes ●
	No ○
Indication	PROPHYLAXIS FOR MRSA
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)*	15 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	20 OCT 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 ⬤

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) **05 Apr 2021 19:48:11**

Generated On: 09 Jun 2021 16:17:00

Name of Medication	TICAGRELOR

Prophylaxis	
	Yes ●
	No ○

Indication	ACUTE CORONARY SYNDROME
Dose per administration	90

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)*   15 OCT 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)   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 (14)

Data signed: (b) (4) **05 Apr 2021 19:48:11**

Generated On: 09 Jun 2021 16:17:00

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes ⚪
	No ⚫
Indication	INJECTION SITE PAIN
Dose per administration	650
Dose unit	mg ⚫
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚪
If dose unit is Other, specify	
Frequency	once daily ⚪
	twice daily ⚪
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚫
	once ⚪
	unknown ⚪
	other ⚪
If frequency is Other, specify	
Route of administration	Oral ⚫
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪
	Intraocular ⚪

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)*	15 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	20 OCT 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 (15)

Data signed: (b) (4) **05 Apr 2021 19:48:11**

Generated On: 09 Jun 2021 16:17:00

Name of Medication	DEXTROSE/WATER
Prophylaxis	Yes ●
	No ○
Indication	DEHYDRATION
Dose per administration	25
Dose unit	mg ○
	ug ○
	mL ●
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ○
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ●
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ○
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

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)*	15 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	20 OCT 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 ◯

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) **05 Apr 2021 19:48:11**

Generated On: 09 Jun 2021 16:17:00

Name of Medication	GLUCAGON

Prophylaxis

Yes ⚪
No ⬤

Indication	HYPOGLYCAEMIA
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 ⚪

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Data signed: (b) (4) **05 Apr 2021 19:48:11**
Generated On: 09 Jun 2021 16:17:00

	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)*	15 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	20 OCT 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 (17)

Data signed: (b) (4) **05 Apr 2021 19:48:11**

Generated On: 09 Jun 2021 16:17:00

Name of Medication	ONDANSETRON

Prophylaxis

Yes ●

No ○

Indication	NAUSEA
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)*	15 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ○
	No ●

If not Ongoing, End date *(dd MMM yyyy)*	20 OCT 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 ○

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) **05 Apr 2021 19:48:11**

Generated On: 09 Jun 2021 16:17:00

Name of Medication	INFLUENZA VACCINE

Prophylaxis	Yes ⬤
	No ⭕

Indication	GENERAL HEALTH

Dose per administration	180

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

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

	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)*	15 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ○
	No ●

If not Ongoing, End date *(dd MMM yyyy)*	15 OCT 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 (19)
Data signed: (b) (4) **05 Apr 2021 19:48:11**
Generated On: 09 Jun 2021 16:17:00

Name of Medication	PNEUMOCOCCAL VACCINE
Prophylaxis	Yes ●
	No ○
Indication	GENERAL HEALTH
Dose per administration	0.5
Dose unit	mg ○
	ug ○
	mL ●
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ○
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ●
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ○
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Data signed: (b) (4) **05 Apr 2021 19:48:11**
Generated On: 09 Jun 2021 16:17:00

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)*	15 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	15 OCT 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 ○

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) **05 Apr 2021 19:48:11**

Generated On: 09 Jun 2021 16:17:00

Name of Medication	AMIODARONE HCL
Prophylaxis	Yes ⚪
	No ⚫
Indication	ACUTE CORONARY SYNDROME
Dose per administration	100
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 ⚪

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Data signed: (b) (4) **05 Apr 2021 19:48:11**
Generated On: 09 Jun 2021 16:17:00

	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)*	15 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ⭕
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	20 OCT 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 (21)

Data signed: (b) (4) **05 Apr 2021 19:48:11**

Generated On: 09 Jun 2021 16:17:00

Name of Medication	CARVEDILOL

Prophylaxis	Yes	●
	No	◯

Indication	PROPHYLAXIS FOR HEART FAILURE

Dose per administration	3.12

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)*	20 OCT 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)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

US3252119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **05 Mar 2021 20:13:47**

Generated On: 09 Jun 2021 16:17:00

Were any concomitant procedures performed?   Yes ●

No ◯

If yes, please complete Concomitant Procedures form.

US3252119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **05 Mar 2021 20:13:46**

Generated On: 09 Jun 2021 16:17:00

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
14 OCT 2020	EMERGENT LEFT HEART CATHERIZATION	Adverse Event	
14 OCT 2020	PERCUTANEOUS CORONARY INTERVENTION TO THE CIRCUMFLEX AND LEFT POSTERIOR DESCENDING ARTERY	Adverse Event	
15 OCT 2020	PERCUTANEOUS CORONARY INTERVENTION TO LEFT ANTERIOR DESCENDING ARTERY	Adverse Event	
14 OCT 2020	ATTEMPTED PERCUTANEOUS CORONARY INTERVENTION TO THE RAMUS UNABLE TO CROSS	Adverse Event	

US3252119
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 16:17:00

Date of dosing discontinuation (dd MMM yyyy) _____

Primary reason for dosing discontinuation

AE (specify) ◯
SAE (specify) ◯
Death ◯
Lost To Follow-up ◯
Physician decision (specify) ◯
Pregnancy ◯
Protocol deviation (specify) ◯
Study Terminated By Sponsor ◯
Withdrawal of consent by participant (specify) ◯
Due to SARS-COV-2 ◯
Other ◯

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

US3252119
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:17:00

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-US108-2020-MRNA-1273-P30 1000006
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	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	78504
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form (1)
Data signed: (b) (4) **05 Mar 2021 20:13:47**
Generated On: 09 Jun 2021 16:17:00

SAEID	USA-US108-2020-MRNA-1273-P30 1000006
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	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	78504
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	21/OCT/2020 20:37
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

Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form (2)
Data signed: (b) (4) **05 Mar 2021 20:13:47**
Generated On: 09 Jun 2021 16:17:00

SAEID	USA-US108-2020-MRNA-1273-P30 1000006
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	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	78504
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	16/NOV/2020 22:14
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-US108-2020-MRNA-1273-P30 1000006
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	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	78504
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	18/NOV/2020 13:21
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

Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form (4)
Data signed: (b) (4) **05 Mar 2021 20:13:47**
Generated On: 09 Jun 2021 16:17:00

SAEID	USA-US108-2020-MRNA-1273-P30 1000006
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	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	78504
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	24/NOV/2020 18:52
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

Audit

US3252119 (Prod: Centex Studies Inc)

US3252119

Form: Participant Creation

Generated On: 09 Jun 2021 16:17:00

Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'US3252119'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:44:46

US3252119

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:17:00

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:36

US3252119
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:17:00

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:44:47

US3252119

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Clinic (Clinic)'	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:36

US3252119
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:17:00
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered 'SCRN'	System	11 Aug 2020 18:49:36

Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:17:00
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered (b) (6) 1963'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:44:48

US3252119
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:17:00

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '57'	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:47

US3252119
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:17:00
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered 'YEARS'	System	11 Aug 2020 18:49:47

US3252119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:00

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered '57'	System	11 Aug 2020 18:00:24

US3252119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:00

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Male (M)'	Xavier Morales (b) (4)	11 Aug 2020 18:49:47
	(b) (4)	

US3252119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:00

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:47

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '1'	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:47

US3252119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:00

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Xavier Morales (b) (4)	11 Aug 2020 18:49:47
	(b) (4)	

US3252119
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:17:00
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:47

US3252119
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:17:00

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:47

US3252119
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:17:00
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Xavier Morales (b) (4)	11 Aug 2020 18:49:47
	(b) (4)	

US3252119
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:17:00
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:47

US3252119
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:17:00
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:47

Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:17:00
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:47

FDA-CBER-2022-1614-0713987

US3252119
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:17:00
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Xavier Morales (b) (4)	11 Aug 2020 18:49:47
	(b) (4)	

US3252119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:17:00

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '11 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	11 Aug 2020 18:00:24

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered 'Aug 2020'	System	11 Aug 2020 18:00:24

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered '2020'	System	11 Aug 2020 18:00:24

US3252119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:17:00

Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 18:49:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 18:49:55
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:55
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 18:00:24
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Aug 2020 18:00:24

US3252119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:17:00

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 18:00:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 18:00:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	11 Aug 2020 18:00:32
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 18:00:24
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Aug 2020 18:00:24

US3252119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:17:00

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Joanna Gurrola Mahoney	11 Aug 2020 18:00:24
	(b) (4)	

US3252119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:17:00

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Aug 2020 18:00:24

US3252119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:17:00

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 18:49:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 18:49:55
User entered 'No (N)' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:55
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 18:00:24
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Aug 2020 18:00:24

US3252119
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:17:00
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	RWS_ENDPOINT	11 Aug 2020 16:44:47
	ENDPOINT (b) (4)	

US3252119
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:17:00
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered '1'	System	11 Aug 2020 18:00:32
User entered empty.	System	11 Aug 2020 18:00:24

US3252119

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:17:00

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	11 Aug 2020 17:50:57

Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 16:17:00

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	12 Aug 2020 14:22:35
	(b) (4)	

US3252119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:17:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:25:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:25:14
Data point term sent to Coder	System	12 Aug 2020 14:23:51
User entered 'Type II Diabetes'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:23:11

Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:17:00
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'UN UNK 2016'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:23:11

US3252119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:23:11

US3252119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:17:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:23:11

US3252119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Shannon Moyer (b) (4)	12 Aug 2020 14:23:11
	(b) (4)	

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:17:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Shannon Moyer (b) (4)	12 Aug 2020 14:23:11
	(b) (4)	

US3252119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:17:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered 'Jan 2016'	System	12 Aug 2020 14:23:11

US3252119
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:17:00
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered '2016'	System	12 Aug 2020 14:23:11

US3252119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:17:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered empty.	System	12 Aug 2020 14:23:11

US3252119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:17:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered empty.	System	12 Aug 2020 14:23:11

US3252119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:17:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:26:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:26:08
Data point term sent to Coder	System	12 Aug 2020 14:24:52
User entered 'Hyperlipidemia'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:24:02

Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:17:00
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'UN UNK 2016'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:24:02

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Shannon Moyer (b) (4)	12 Aug 2020 14:24:02
	(b) (4)	

US3252119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:17:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:24:02

US3252119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:24:02

US3252119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:17:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Shannon Moyer (b) (4)	12 Aug 2020 14:24:02
	(b) (4)	

US3252119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:17:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered 'Jan 2016'	System	12 Aug 2020 14:24:02

US3252119
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:17:00
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered '2016'	System	12 Aug 2020 14:24:02

US3252119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:17:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered empty.	System	12 Aug 2020 14:24:02

US3252119
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:17:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered empty.	System	12 Aug 2020 14:24:02

US3252119

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:17:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:26:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:26:08
Data point term sent to Coder	System	12 Aug 2020 14:24:55
User entered 'Hypertension'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:24:45

Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:17:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'UN UNK 2016'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:24:45

US3252119
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:17:00
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:24:45

US3252119
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:17:00
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:24:45

Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:24:45

Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:17:00
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:24:45

US3252119

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:17:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered 'Jan 2016'	System	12 Aug 2020 14:24:45

US3252119

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:17:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered '2016'	System	12 Aug 2020 14:24:45

Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:17:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered empty.	System	12 Aug 2020 14:24:45

US3252119

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:17:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered empty.	System	12 Aug 2020 14:24:45

US3252119
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:17:00
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) and type of FOOT INFECTION. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 20:26:48
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Localised infection, LLT: Foot infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 00:21:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 00:21:44
Data point term sent to Coder	System	23 Sep 2020 18:25:50
Query 'Per DM CLR: Please specify the location (bilateral, left, right) and type of FOOT INFECTION. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'has been updated' (Site from DM).	Xavier Morales (b) (4) (b) (4)	23 Sep 2020 18:25:00
Coding entries removed.	Xavier Morales (b) (4) (b) (4)	23 Sep 2020 18:24:55
User entered 'LEFT FOOT INFECTION' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	23 Sep 2020 18:24:55
User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) and type of FOOT INFECTION. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 16:17:22
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Localised infection, LLT: Foot infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:26:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:26:08
Data point term sent to Coder	System	12 Aug 2020 14:25:55

Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:17:00
Condition

Audit	User	Time (GMT)
User entered 'Foot infection'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:25:05

US3252119

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:17:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'UN Apr 2020'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:25:05

Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:17:00
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Shannon Moyer (b) (4)	12 Aug 2020 14:25:05
	(b) (4)	

US3252119
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:17:00
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:25:05

US3252119

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Shannon Moyer (b) (4)	12 Aug 2020 14:25:05
	(b) (4)	

US3252119

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:17:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:25:05

US3252119

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:17:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered 'Apr 2020'	System	12 Aug 2020 14:25:05

US3252119

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:17:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered '2020'	System	12 Aug 2020 14:25:05

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered empty.	System	12 Aug 2020 14:25:05

US3252119
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:17:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered empty.	System	12 Aug 2020 14:25:05

US3252119

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:17:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Toe amputation, LLT: Toe amputation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 13:09:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 13:09:04
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 20:27:08
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'has been updated' (Site from DM).	Xavier Morales (b) (4) (b) (4)	23 Sep 2020 18:26:11
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 16:17:52
Data point term sent to Coder	System	23 Aug 2020 03:14:47
User entered 'Removal of fifth left toe'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:04:13

US3252119

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:17:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'UN Nov 2016'	Joanna Gurrola Mahoney	23 Aug 2020 02:04:13
	(b) (4)	

US3252119
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:17:00
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:04:13

US3252119
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:17:00
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:04:13

US3252119

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'UN Nov 2016'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:04:13

US3252119
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:17:00
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:04:13

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered 'Nov 2016'	System	23 Aug 2020 02:04:13

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:17:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered '2016'	System	23 Aug 2020 02:04:13

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:17:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered 'Nov 2016'	System	23 Aug 2020 02:04:13

US3252119

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:17:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered '2016'	System	23 Aug 2020 02:04:13

US3252119

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:17:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
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)	23 Aug 2020 03:17:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Aug 2020 03:17:27
Data point term sent to Coder	System	23 Aug 2020 03:14:54
User entered 'Vasectomy'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:05:04

US3252119
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:17:00
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'UN Jan 2000'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:05:04

Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:17:00
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:05:04

US3252119
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:17:00
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:05:04

US3252119
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:17:00
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'UN Jan 2000'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:05:04

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:05:04

US3252119

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:17:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered 'Jan 2000'	System	23 Aug 2020 02:05:04

US3252119

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:17:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered '2000'	System	23 Aug 2020 02:05:04

US3252119

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:17:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered 'Jan 2000'	System	23 Aug 2020 02:05:04

US3252119

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:17:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered '2000'	System	23 Aug 2020 02:05:04

US3252119

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:17:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Localised infection, LLT: Foot infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 00:21:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 00:21:44
Data point term sent to Coder	System	23 Sep 2020 18:25:52
User entered 'Left foot infection'	Xavier Morales (b) (4) (b) (4)	23 Sep 2020 18:25:31

US3252119

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:17:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'UN Nov 2016'	Xavier Morales (b) (4)	23 Sep 2020 18:25:31
	(b) (4)	

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Xavier Morales (b) (4) (b) (4)	23 Sep 2020 18:25:31

US3252119

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:17:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Xavier Morales (b) (4) (b) (4)	23 Sep 2020 18:25:31

US3252119

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'UN Nov 2016'	Xavier Morales (b) (4)	23 Sep 2020 18:25:31
	(b) (4)	

Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:17:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Xavier Morales (b) (4) (b) (4)	23 Sep 2020 18:25:31

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:17:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered 'Nov 2016'	System	23 Sep 2020 18:25:31

US3252119

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:17:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered '2016'	System	23 Sep 2020 18:25:31

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:17:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered 'Nov 2016'	System	23 Sep 2020 18:25:31

US3252119
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:17:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered '2016'	System	23 Sep 2020 18:25:31

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:27:03

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '11 Aug 2020'	Shannon Moyer (b) (4)	12 Aug 2020 14:27:03
	(b) (4)	

US3252119
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '11:32'	Shannon Moyer (b) (4)	12 Aug 2020 14:27:03
	(b) (4)	

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered '11 Aug 2020 11:32'	System	12 Aug 2020 14:27:03

US3252119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:00

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '71.3' in	Shannon Moyer (b) (4)	12 Aug 2020 14:27:03
	(b) (4)	
DataPoint set to visible.	System	11 Aug 2020 18:00:32

US3252119
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '313' lb	Shannon Moyer (b) (4)	12 Aug 2020 14:27:03
DataPoint set to visible.	(b) (4) System	11 Aug 2020 18:00:32

FDA-CBER-2022-1614-0714077

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
Amendment Manager: User entered '43.37856'	System	16 Sep 2020 23:51:50
User entered '43.4'	System	12 Aug 2020 14:27:03
DataPoint set to visible.	System	11 Aug 2020 18:00:32

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered 'kg/m2'	System	12 Aug 2020 14:27:03
DataPoint set to visible.	System	11 Aug 2020 18:00:32

US3252119
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 01:58:57
User entered '98.2' F	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:27:03

US3252119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:00

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 01:58:57
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:27:03

US3252119
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:27:03

US3252119
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 01:58:57
User entered '81'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:27:03

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered 'bpm'	System	12 Aug 2020 14:27:03

US3252119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:00

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 01:58:57
User entered '16'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:27:03

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered 'breaths/min'	System	12 Aug 2020 14:27:03

US3252119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:00

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 01:58:57
User entered '134'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:27:03

US3252119
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered 'mmHg'	System	12 Aug 2020 14:27:03

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 01:58:57
User entered '90'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:27:03

US3252119
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User entered 'mmHg'	System	12 Aug 2020 14:27:03

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27

US3252119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:00

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27

US3252119

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:00

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:27:15

US3252119

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:00

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 14:37:33
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 05:25:23
User entered '11 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:27:15

US3252119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:28:06

US3252119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Shannon Moyer (b) (4)	12 Aug 2020 14:28:06
	(b) (4)	

US3252119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:00

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)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:28:06

US3252119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:00

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)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:28:06

US3252119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:28:06

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:00

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)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:28:06

US3252119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:00

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)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:28:06

US3252119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:00

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)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:28:06

US3252119
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:17:00
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)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Shannon Moyer (b) (4)	12 Aug 2020 14:28:06
	(b) (4)	

US3252119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:00

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)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:28:06

US3252119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:00

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)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:28:06

US3252119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:00

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:28:06

US3252119
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:17:00
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'GM (b) (6) '	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:28:06

US3252119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:00

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:28:06

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:00

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:28:06

US3252119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:00

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)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:28:06

US3252119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:00

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)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:28:06

US3252119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:00

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)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:28:06

US3252119
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:17:00
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '1'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:28:06

US3252119
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:17:00
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '0'	Shannon Moyer (b) (4)	12 Aug 2020 14:28:06
	(b) (4)	

US3252119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:00

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:21:27
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:28:06

US3252119
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:17:00
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:28

US3252119

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:17:00

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '11 Aug 2020'	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:28

US3252119

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Clinic (Clinic)'	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:28

US3252119
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:17:00
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered 'VISIT1'	System	11 Aug 2020 18:49:28

US3252119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:49:58

US3252119
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:17:00

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:35:51
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:35:51
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 16:49:58
User entered '143657' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:49:58

US3252119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:17:00

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:49:58

US3252119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:17:00

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)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:17

US3252119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:17:00

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)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:17

Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:17

Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:17:00

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Xavier Morales (b) (4)	11 Aug 2020 18:49:17
	(b) (4)	

US3252119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:17:00

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Xavier Morales (b) (4) (b) (4)	11 Aug 2020 18:49:17

US3252119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:17:00

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Nancy Torrence (b) (4)	30 Sep 2020 04:58:14
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:31:53

US3252119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:17:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:07:08
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:22:17
User entered '71.3' in	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

US3252119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:17:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:07:08
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:22:17
User entered '313' lb	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

US3252119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:17:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:07:08
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:22:17
User entered '71.3' in	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

US3252119
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:17:00
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:07:08
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:22:17
User entered '313' lb	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

US3252119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

US3252119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

US3252119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '11 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '11:32'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered '11 Aug 2020 11:32'	System	12 Aug 2020 14:29:37

US3252119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '98.2' F	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

US3252119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

US3252119
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:17:00
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

US3252119
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:17:00

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '81'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered 'bpm'	System	12 Aug 2020 14:29:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '16'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered 'breaths/min'	System	12 Aug 2020 14:29:37

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '134'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered 'mmHg'	System	12 Aug 2020 14:29:37

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:17:00

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '90'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered 'mmHg'	System	12 Aug 2020 14:29:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:17:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:07:08
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:22:17
User entered '71.3' in	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

US3252119
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:17:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:07:08
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:22:17
User entered '313' lb	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

US3252119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

US3252119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 20:22:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 20:22:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:22:17
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 14:29:37
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '11 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:22:17
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:35:48
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per Source, correct as is' (Site from System).	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:22:34
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	20 Aug 2020 20:22:17
User entered '13:12' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:22:17
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered '11 Aug 2020 13:12'	System	20 Aug 2020 20:22:17
User entered empty.	System	12 Aug 2020 14:29:37

US3252119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '97.6' F reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:22:17
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

US3252119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Oral (Oral)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:22:17
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

US3252119
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:17:00
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '77' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:22:17
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered 'bpm'	System	20 Aug 2020 20:22:17
User entered empty.	System	12 Aug 2020 14:29:37

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:17:00

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '16' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:22:17
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered 'breaths/min'	System	20 Aug 2020 20:22:17
User entered empty.	System	12 Aug 2020 14:29:37

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '130' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:22:17
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered 'mmHg'	System	20 Aug 2020 20:22:17
User entered empty.	System	12 Aug 2020 14:29:37

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '84' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:22:17
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered 'mmHg'	System	20 Aug 2020 20:22:17
User entered empty.	System	12 Aug 2020 14:29:37

US3252119

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:00

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 01:59:29
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:51

US3252119

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:00

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 01:59:29
User entered '11 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:29:51

US3252119
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:17:00
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	20 Aug 2020 20:22:58
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	20 Aug 2020 20:22:58
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 14:30:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 14:30:07
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	12 Aug 2020 14:30:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:30:07
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 18:01:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Aug 2020 18:01:00

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Aug 2020 18:01:00

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

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)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Aug 2020 18:01:00

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Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:17:00
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 14:30:07
User entered empty.	System	11 Aug 2020 18:01:00

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '11 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	11 Aug 2020 18:01:00

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '12:25'	Joanna Gurrola Mahoney (b) (4)	11 Aug 2020 18:01:00

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered '11 Aug 2020 12:25'	System	11 Aug 2020 18:01:00

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Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:17:00

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:22:58
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Aug 2020 18:01:00

US3252119
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:17:00
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered 'ONCE'	System	12 Aug 2020 14:30:07
User entered empty.	System	11 Aug 2020 18:01:00

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:17:00

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 14:30:07
User entered empty.	System	11 Aug 2020 18:01:00

US3252119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:00

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:30:32

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:00

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '11 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:30:32

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '12:00'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:30:32

US3252119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered '11 Aug 2020 12:00'	System	12 Aug 2020 14:30:32

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '11 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:30:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:17:00

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:30:55

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:17:00
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:30:55

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '11:49'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:30:55

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:17:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered '11 Aug 2020 11:49'	System	12 Aug 2020 14:30:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:17:00

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:30:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:17:00

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:30:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:30:55

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered empty.	System	12 Aug 2020 14:30:55

FDA-CBER-2022-1614-0714191

US3252119
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:31:02

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered '1'	System	12 Aug 2020 14:31:02

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-11T13:01:58', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '0356e223-84d3-4cb1-b83b-4111f833b3db'	System	11 Aug 2020 18:02:18
User entered 'Yes (Y)'	System	11 Aug 2020 18:02:18

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-11T13:02:06', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '0356e223-84d3-4cb1-b83b-4111f833b3db'	System	11 Aug 2020 18:02:18
User entered '97.6'	System	11 Aug 2020 18:02:18

US3252119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-11T13:02:10', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '0356e223-84d3-4cb1-b83b-4111f833b3db'	System	11 Aug 2020 18:02:18
User entered 'No (N)'	System	11 Aug 2020 18:02:18

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-11T13:02:15', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '0356e223-84d3-4cb1-b83b-4111f833b3db'	System	11 Aug 2020 18:02:18
User entered '11 Aug 2020 13:02'	System	11 Aug 2020 18:02:18

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '11 Aug 2020 12:45'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '11 Aug 2020 15:15'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 18:01:00

Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

FDA-CBER-2022-1614-0714204

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:17:00

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '11 Aug 2020 16:10'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 2'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:17:00
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-13T09:36:22', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '1e366ad3-a274-4f50-aac1-0c1519b53ce3'	System	13 Aug 2020 14:37:30
User entered 'Yes (Y)'	System	13 Aug 2020 14:37:30

US3252119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-13T09:36:31', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '1e366ad3-a274-4f50-aac1-0c1519b53ce3'	System	13 Aug 2020 14:37:30
User entered '97.6'	System	13 Aug 2020 14:37:30

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-13T09:37:11', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '1e366ad3-a274-4f50-aac1-0c1519b53ce3'	System	13 Aug 2020 14:37:30
User entered 'No (N)'	System	13 Aug 2020 14:37:30

FDA-CBER-2022-1614-0714213

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-13T09:37:24', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '1e366ad3-a274-4f50-aac1-0c1519b53ce3'	System	13 Aug 2020 14:37:30
User entered '13 Aug 2020 09:37'	System	13 Aug 2020 14:37:30

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 18:01:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

FDA-CBER-2022-1614-0714216

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 3'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-14T07:54:48', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'f9754268-25bd-4eb2-b6a7-f0077fc61c43'	System	14 Aug 2020 12:55:19
User entered 'Yes (Y)'	System	14 Aug 2020 12:55:19

US3252119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-14T07:55:01', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'f9754268-25bd-4eb2-b6a7-f0077fc61c43'	System	14 Aug 2020 12:55:19
User entered '96.1'	System	14 Aug 2020 12:55:19

US3252119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-14T07:55:06', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'f9754268-25bd-4eb2-b6a7-f0077fc61c43'	System	14 Aug 2020 12:55:19
User entered 'No (N)'	System	14 Aug 2020 12:55:19

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:17:00

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-14T07:55:16', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'f9754268-25bd-4eb2-b6a7-f0077fc61c43'	System	14 Aug 2020 12:55:19
User entered '14 Aug 2020 07:55'	System	14 Aug 2020 12:55:19

US3252119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 4'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:17:00
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-15T10:29:51', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '061fc237-b8e5-4ddd-9962-1aa2a96808f1'	System	15 Aug 2020 15:30:11
User entered 'Yes (Y)'	System	15 Aug 2020 15:30:11

FDA-CBER-2022-1614-0714225

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:17:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-15T10:29:56', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '061fc237-b8e5-4ddd-9962-1aa2a96808f1'	System	15 Aug 2020 15:30:11
User entered '96.6'	System	15 Aug 2020 15:30:11

US3252119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-15T10:30:04', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '061fc237-b8e5-4ddd-9962-1aa2a96808f1'	System	15 Aug 2020 15:30:11
User entered 'No (N)'	System	15 Aug 2020 15:30:11

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-15T10:30:08', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '061fc237-b8e5-4ddd-9962-1aa2a96808f1'	System	15 Aug 2020 15:30:11
User entered '15 Aug 2020 10:30'	System	15 Aug 2020 15:30:11

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:17:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:17:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 5'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T06:02:56', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7d2d0920-19d3-4b5e-a98d-0d27dc441f6e'	System	16 Aug 2020 11:03:23
User entered 'Yes (Y)'	System	16 Aug 2020 11:03:23

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:17:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T06:03:10', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7d2d0920-19d3-4b5e-a98d-0d27dc441f6e'	System	16 Aug 2020 11:03:23
User entered '96.9'	System	16 Aug 2020 11:03:23

US3252119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T06:03:15', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7d2d0920-19d3-4b5e-a98d-0d27dc441f6e'	System	16 Aug 2020 11:03:23
User entered 'No (N)'	System	16 Aug 2020 11:03:23

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T06:03:18', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7d2d0920-19d3-4b5e-a98d-0d27dc441f6e'	System	16 Aug 2020 11:03:23
User entered '16 Aug 2020 06:03'	System	16 Aug 2020 11:03:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 18:01:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

FDA-CBER-2022-1614-0714237

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 6'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:17:00
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T21:42:02', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '82eca7e9-0d05-418e-a0ae-2f222ce08133'	System	17 Aug 2020 02:42:18
User entered 'Yes (Y)'	System	17 Aug 2020 02:42:18

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:17:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T21:42:08', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '82eca7e9-0d05-418e-a0ae-2f222ce08133'	System	17 Aug 2020 02:42:18
User entered '96.2'	System	17 Aug 2020 02:42:18

US3252119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T21:42:13', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '82eca7e9-0d05-418e-a0ae-2f222ce08133'	System	17 Aug 2020 02:42:18
User entered 'No (N)'	System	17 Aug 2020 02:42:18

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T21:42:16', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '82eca7e9-0d05-418e-a0ae-2f222ce08133'	System	17 Aug 2020 02:42:18
User entered '16 Aug 2020 21:42'	System	17 Aug 2020 02:42:18

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 7'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:17:00
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-18T07:31:55', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'd3016cb3-0c31-434a-833b-e9f88e61d8d3'	System	18 Aug 2020 12:33:28
User entered 'Yes (Y)'	System	18 Aug 2020 12:33:28

US3252119
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:17:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-18T07:32:11', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'd3016cb3-0c31-434a-833b-e9f88e61d8d3'	System	18 Aug 2020 12:33:28
User entered '97.1'	System	18 Aug 2020 12:33:28

US3252119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-18T07:33:16', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'd3016cb3-0c31-434a-833b-e9f88e61d8d3'	System	18 Aug 2020 12:33:28
User entered 'No (N)'	System	18 Aug 2020 12:33:28

US3252119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:00

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-18T07:33:26', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'd3016cb3-0c31-434a-833b-e9f88e61d8d3'	System	18 Aug 2020 12:33:28
User entered '18 Aug 2020 07:33'	System	18 Aug 2020 12:33:28

US3252119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-11T13:02:22', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8e3b823b-23fd-4240-b9bd-92ce20391d06'	System	11 Aug 2020 18:02:38
User entered 'None (1)'	System	11 Aug 2020 18:02:38

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-11T13:02:25', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8e3b823b-23fd-4240-b9bd-92ce20391d06'	System	11 Aug 2020 18:02:38
User entered 'No (N)'	System	11 Aug 2020 18:02:38

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-11T13:02:27', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8e3b823b-23fd-4240-b9bd-92ce20391d06'	System	11 Aug 2020 18:02:38
User entered 'No (N)'	System	11 Aug 2020 18:02:38

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-11T13:02:30', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8e3b823b-23fd-4240-b9bd-92ce20391d06'	System	11 Aug 2020 18:02:38
User entered 'None (1)'	System	11 Aug 2020 18:02:38

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-11T13:02:35', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8e3b823b-23fd-4240-b9bd-92ce20391d06'	System	11 Aug 2020 18:02:38
User entered '11 Aug 2020 13:02'	System	11 Aug 2020 18:02:38

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '11 Aug 2020 12:45'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '11 Aug 2020 15:15'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '11 Aug 2020 16:10'	System	11 Aug 2020 18:01:00

Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 2'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-13T09:37:34', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'fe2eca71-2181-4c8c-8ba6-2144c6742aae'	System	13 Aug 2020 14:38:01
User entered 'None (1)'	System	13 Aug 2020 14:38:01

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-13T09:37:39', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'fe2eca71-2181-4c8c-8ba6-2144c6742aae'	System	13 Aug 2020 14:38:01
User entered 'No (N)'	System	13 Aug 2020 14:38:01

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-13T09:37:43', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'fe2eca71-2181-4c8c-8ba6-2144c6742aae'	System	13 Aug 2020 14:38:01
User entered 'No (N)'	System	13 Aug 2020 14:38:01

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-13T09:37:55', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'fe2eca71-2181-4c8c-8ba6-2144c6742aae'	System	13 Aug 2020 14:38:01
User entered 'None (1)'	System	13 Aug 2020 14:38:01

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-13T09:37:59', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'fe2eca71-2181-4c8c-8ba6-2144c6742aae'	System	13 Aug 2020 14:38:01
User entered '13 Aug 2020 09:37'	System	13 Aug 2020 14:38:01

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 18:01:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

FDA-CBER-2022-1614-0714277

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 3'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-14T07:55:35', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'cef42015-a162-42ab-9ba7-b443bb7c555f'	System	14 Aug 2020 12:56:03
User entered 'None (1)'	System	14 Aug 2020 12:56:03

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:17:00
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-14T07:55:40', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'cef42015-a162-42ab-9ba7-b443bb7c555f'	System	14 Aug 2020 12:56:03
User entered 'No (N)'	System	14 Aug 2020 12:56:03

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:17:00
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-14T07:55:46', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'cef42015-a162-42ab-9ba7-b443bb7c555f'	System	14 Aug 2020 12:56:03
User entered 'No (N)'	System	14 Aug 2020 12:56:03

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-14T07:55:53', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'cef42015-a162-42ab-9ba7-b443bb7c555f'	System	14 Aug 2020 12:56:03
User entered 'None (1)'	System	14 Aug 2020 12:56:03

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-14T07:55:58', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'cef42015-a162-42ab-9ba7-b443bb7c555f'	System	14 Aug 2020 12:56:03
User entered '14 Aug 2020 07:55'	System	14 Aug 2020 12:56:03

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 18:01:00

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 4'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-15T10:30:14', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '88e02dd9-8b4f-4a95-a2ec-d150b5c2bce5'	System	15 Aug 2020 15:30:40
User entered 'None (1)'	System	15 Aug 2020 15:30:40

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:17:00
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-15T10:30:18', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '88e02dd9-8b4f-4a95-a2ec-d150b5c2bce5'	System	15 Aug 2020 15:30:40
User entered 'No (N)'	System	15 Aug 2020 15:30:40

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-15T10:30:25', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '88e02dd9-8b4f-4a95-a2ec-d150b5c2bce5'	System	15 Aug 2020 15:30:40
User entered 'No (N)'	System	15 Aug 2020 15:30:40

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-15T10:30:33', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '88e02dd9-8b4f-4a95-a2ec-d150b5c2bce5'	System	15 Aug 2020 15:30:40
User entered 'None (1)'	System	15 Aug 2020 15:30:40

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-15T10:30:35', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '88e02dd9-8b4f-4a95-a2ec-d150b5c2bce5'	System	15 Aug 2020 15:30:40
User entered '15 Aug 2020 10:30'	System	15 Aug 2020 15:30:40

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 18:01:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 5'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T06:03:25', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '3b658289-2eb4-439f-b776-8eb60a8c43f0'	System	16 Aug 2020 11:03:48
User entered 'None (1)'	System	16 Aug 2020 11:03:48

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:17:00
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T06:03:29', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '3b658289-2eb4-439f-b776-8eb60a8c43f0'	System	16 Aug 2020 11:03:48
User entered 'No (N)'	System	16 Aug 2020 11:03:48

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T06:03:34', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '3b658289-2eb4-439f-b776-8eb60a8c43f0'	System	16 Aug 2020 11:03:48
User entered 'No (N)'	System	16 Aug 2020 11:03:48

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T06:03:42', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '3b658289-2eb4-439f-b776-8eb60a8c43f0'	System	16 Aug 2020 11:03:48
User entered 'None (1)'	System	16 Aug 2020 11:03:48

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:00

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T06:03:47', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '3b658289-2eb4-439f-b776-8eb60a8c43f0'	System	16 Aug 2020 11:03:48
User entered '16 Aug 2020 06:03'	System	16 Aug 2020 11:03:48

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 6'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T21:42:23', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7906be26-d704-4a70-a1e3-5b5847908ee3'	System	17 Aug 2020 02:42:36
User entered 'None (1)'	System	17 Aug 2020 02:42:36

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T21:42:27', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7906be26-d704-4a70-a1e3-5b5847908ee3'	System	17 Aug 2020 02:42:36
User entered 'No (N)'	System	17 Aug 2020 02:42:36

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T21:42:29', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7906be26-d704-4a70-a1e3-5b5847908ee3'	System	17 Aug 2020 02:42:36
User entered 'No (N)'	System	17 Aug 2020 02:42:36

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T21:42:33', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7906be26-d704-4a70-a1e3-5b5847908ee3'	System	17 Aug 2020 02:42:36
User entered 'None (1)'	System	17 Aug 2020 02:42:36

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T21:42:35', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7906be26-d704-4a70-a1e3-5b5847908ee3'	System	17 Aug 2020 02:42:36
User entered '16 Aug 2020 21:42'	System	17 Aug 2020 02:42:36

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 7'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-18T07:33:54', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6e033303-3863-4797-a4ca-a963a5aa7a29'	System	18 Aug 2020 12:34:22
User entered 'None (1)'	System	18 Aug 2020 12:34:22

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-18T07:33:59', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6e033303-3863-4797-a4ca-a963a5aa7a29'	System	18 Aug 2020 12:34:22
User entered 'No (N)'	System	18 Aug 2020 12:34:22

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:17:00
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-18T07:34:09', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6e033303-3863-4797-a4ca-a963a5aa7a29'	System	18 Aug 2020 12:34:22
User entered 'No (N)'	System	18 Aug 2020 12:34:22

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-18T07:34:17', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6e033303-3863-4797-a4ca-a963a5aa7a29'	System	18 Aug 2020 12:34:22
User entered 'None (1)'	System	18 Aug 2020 12:34:22

US3252119
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-18T07:34:19', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6e033303-3863-4797-a4ca-a963a5aa7a29'	System	18 Aug 2020 12:34:22
User entered '18 Aug 2020 07:34'	System	18 Aug 2020 12:34:22

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 18:01:00

FDA-CBER-2022-1614-0714316

US3252119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-11T13:02:40', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8420ae21-d5ee-4587-b29b-fd479f47282b'	System	11 Aug 2020 18:03:06
User entered 'None (0)'	System	11 Aug 2020 18:03:06

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-11T13:02:44', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8420ae21-d5ee-4587-b29b-fd479f47282b'	System	11 Aug 2020 18:03:06
User entered 'None (0)'	System	11 Aug 2020 18:03:06

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-11T13:02:47', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8420ae21-d5ee-4587-b29b-fd479f47282b'	System	11 Aug 2020 18:03:06
User entered 'None (0)'	System	11 Aug 2020 18:03:06

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-11T13:02:49', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8420ae21-d5ee-4587-b29b-fd479f47282b'	System	11 Aug 2020 18:03:06
User entered 'None (0)'	System	11 Aug 2020 18:03:06

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-11T13:02:53', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8420ae21-d5ee-4587-b29b-fd479f47282b'	System	11 Aug 2020 18:03:06
User entered 'None (0)'	System	11 Aug 2020 18:03:06

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-11T13:02:55', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8420ae21-d5ee-4587-b29b-fd479f47282b'	System	11 Aug 2020 18:03:06
User entered 'None (0)'	System	11 Aug 2020 18:03:06

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-11T13:02:57', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8420ae21-d5ee-4587-b29b-fd479f47282b'	System	11 Aug 2020 18:03:06
User entered 'No (N)'	System	11 Aug 2020 18:03:06

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-11T13:03:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8420ae21-d5ee-4587-b29b-fd479f47282b'	System	11 Aug 2020 18:03:06
User entered '11 Aug 2020 13:03'	System	11 Aug 2020 18:03:06

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '11 Aug 2020 12:45'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '11 Aug 2020 15:15'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:17:00

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 07:07:29

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '11 Aug 2020 16:10'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 2'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-13T09:38:06', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'b012fc3f-a608-4dd3-9665-f0fd7ba5126b'	System	13 Aug 2020 14:38:53
User entered 'None (0)'	System	13 Aug 2020 14:38:53

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-13T09:38:11', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'b012fc3f-a608-4dd3-9665-f0fd7ba5126b'	System	13 Aug 2020 14:38:53
User entered 'None (0)'	System	13 Aug 2020 14:38:53

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-13T09:38:18', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'b012fc3f-a608-4dd3-9665-f0fd7ba5126b'	System	13 Aug 2020 14:38:53
User entered 'None (0)'	System	13 Aug 2020 14:38:53

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-13T09:38:24', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'b012fc3f-a608-4dd3-9665-f0fd7ba5126b'	System	13 Aug 2020 14:38:53
User entered 'None (0)'	System	13 Aug 2020 14:38:53

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-13T09:38:29', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'b012fc3f-a608-4dd3-9665-f0fd7ba5126b'	System	13 Aug 2020 14:38:53
User entered 'None (0)'	System	13 Aug 2020 14:38:53

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-13T09:38:39', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'b012fc3f-a608-4dd3-9665-f0fd7ba5126b'	System	13 Aug 2020 14:38:53
User entered 'None (0)'	System	13 Aug 2020 14:38:53

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-13T09:38:45', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'b012fc3f-a608-4dd3-9665-f0fd7ba5126b'	System	13 Aug 2020 14:38:53
User entered 'No (N)'	System	13 Aug 2020 14:38:53

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-13T09:38:48', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'b012fc3f-a608-4dd3-9665-f0fd7ba5126b'	System	13 Aug 2020 14:38:53
User entered '13 Aug 2020 09:38'	System	13 Aug 2020 14:38:53

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 3'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:17:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-14T07:56:19', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '87cfc266-8700-463d-a41f-afebaeffac60'	System	14 Aug 2020 12:56:51
User entered 'None (0)'	System	14 Aug 2020 12:56:51

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:17:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-14T07:56:24', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '87cfc266-8700-463d-a41f-afebaeffac60'	System	14 Aug 2020 12:56:51
User entered 'None (0)'	System	14 Aug 2020 12:56:51

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:17:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-14T07:56:27', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '87cfc266-8700-463d-a41f-afebaeffac60'	System	14 Aug 2020 12:56:51
User entered 'None (0)'	System	14 Aug 2020 12:56:51

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:17:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-14T07:56:31', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '87cfc266-8700-463d-a41f-afebaeffac60'	System	14 Aug 2020 12:56:51
User entered 'None (0)'	System	14 Aug 2020 12:56:51

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:17:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-14T07:56:34', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '87cfc266-8700-463d-a41f-afebaeffac60'	System	14 Aug 2020 12:56:51
User entered 'None (0)'	System	14 Aug 2020 12:56:51

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:17:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-14T07:56:37', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '87cfc266-8700-463d-a41f-afebaeffac60'	System	14 Aug 2020 12:56:51
User entered 'None (0)'	System	14 Aug 2020 12:56:51

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-14T07:56:45', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '87cfc266-8700-463d-a41f-afebaeffac60'	System	14 Aug 2020 12:56:51
User entered 'No (N)'	System	14 Aug 2020 12:56:51

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-14T07:56:48', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '87cfc266-8700-463d-a41f-afebaeffac60'	System	14 Aug 2020 12:56:51
User entered '14 Aug 2020 07:56'	System	14 Aug 2020 12:56:51

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 4'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-15T10:30:45', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '5c7e2008-c06b-4071-9626-1a0da2fc0dba'	System	15 Aug 2020 15:31:23
User entered 'None (0)'	System	15 Aug 2020 15:31:23

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:17:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-15T10:30:49', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '5c7e2008-c06b-4071-9626-1a0da2fc0dba'	System	15 Aug 2020 15:31:23
User entered 'None (0)'	System	15 Aug 2020 15:31:23

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:17:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-15T10:30:52', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '5c7e2008-c06b-4071-9626-1a0da2fc0dba'	System	15 Aug 2020 15:31:23
User entered 'None (0)'	System	15 Aug 2020 15:31:23

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:17:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-15T10:30:57', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '5c7e2008-c06b-4071-9626-1a0da2fc0dba'	System	15 Aug 2020 15:31:23
User entered 'None (0)'	System	15 Aug 2020 15:31:23

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:17:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-15T10:31:01', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '5c7e2008-c06b-4071-9626-1a0da2fc0dba'	System	15 Aug 2020 15:31:23
User entered 'None (0)'	System	15 Aug 2020 15:31:23

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:17:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-15T10:31:05', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '5c7e2008-c06b-4071-9626-1a0da2fc0dba'	System	15 Aug 2020 15:31:23
User entered 'None (0)'	System	15 Aug 2020 15:31:23

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-15T10:31:15', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '5c7e2008-c06b-4071-9626-1a0da2fc0dba'	System	15 Aug 2020 15:31:23
User entered 'No (N)'	System	15 Aug 2020 15:31:23

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-15T10:31:18', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '5c7e2008-c06b-4071-9626-1a0da2fc0dba'	System	15 Aug 2020 15:31:23
User entered '15 Aug 2020 10:31'	System	15 Aug 2020 15:31:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 5'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:17:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T06:03:51', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7e0599a3-4ffe-4e05-8259-44628eca5c47'	System	16 Aug 2020 11:04:29
User entered 'None (0)'	System	16 Aug 2020 11:04:29

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:17:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T06:03:54', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7e0599a3-4ffe-4e05-8259-44628eca5c47'	System	16 Aug 2020 11:04:29
User entered 'None (0)'	System	16 Aug 2020 11:04:29

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T06:03:58', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7e0599a3-4ffe-4e05-8259-44628eca5c47'	System	16 Aug 2020 11:04:29
User entered 'None (0)'	System	16 Aug 2020 11:04:29

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:17:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T06:04:02', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7e0599a3-4ffe-4e05-8259-44628eca5c47'	System	16 Aug 2020 11:04:29
User entered 'None (0)'	System	16 Aug 2020 11:04:29

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T06:04:06', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7e0599a3-4ffe-4e05-8259-44628eca5c47'	System	16 Aug 2020 11:04:29
User entered 'None (0)'	System	16 Aug 2020 11:04:29

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:17:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T06:04:09', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7e0599a3-4ffe-4e05-8259-44628eca5c47'	System	16 Aug 2020 11:04:29
User entered 'None (0)'	System	16 Aug 2020 11:04:29

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:17:00
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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T06:04:23', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7e0599a3-4ffe-4e05-8259-44628eca5c47'	System	16 Aug 2020 11:04:29
User entered 'No (N)'	System	16 Aug 2020 11:04:29

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T06:04:26', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7e0599a3-4ffe-4e05-8259-44628eca5c47'	System	16 Aug 2020 11:04:29
User entered '16 Aug 2020 06:04'	System	16 Aug 2020 11:04:29

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 18:01:00

FDA-CBER-2022-1614-0714382

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 6'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:17:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T21:42:40', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'b653e027-c867-4598-98dc-749e11e42994'	System	17 Aug 2020 02:43:08
User entered 'None (0)'	System	17 Aug 2020 02:43:08

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:17:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T21:42:42', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'b653e027-c867-4598-98dc-749e11e42994'	System	17 Aug 2020 02:43:08
User entered 'None (0)'	System	17 Aug 2020 02:43:08

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:17:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T21:42:46', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'b653e027-c867-4598-98dc-749e11e42994'	System	17 Aug 2020 02:43:08
User entered 'None (0)'	System	17 Aug 2020 02:43:08

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T21:42:49', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'b653e027-c867-4598-98dc-749e11e42994'	System	17 Aug 2020 02:43:08
User entered 'None (0)'	System	17 Aug 2020 02:43:08

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:17:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T21:42:51', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'b653e027-c867-4598-98dc-749e11e42994'	System	17 Aug 2020 02:43:08
User entered 'None (0)'	System	17 Aug 2020 02:43:08

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:17:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T21:42:54', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'b653e027-c867-4598-98dc-749e11e42994'	System	17 Aug 2020 02:43:08
User entered 'None (0)'	System	17 Aug 2020 02:43:08

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:17:00
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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T21:43:01', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'b653e027-c867-4598-98dc-749e11e42994'	System	17 Aug 2020 02:43:08
User entered 'No (N)'	System	17 Aug 2020 02:43:08

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:17:00
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-16T21:43:03', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'b653e027-c867-4598-98dc-749e11e42994'	System	17 Aug 2020 02:43:08
User entered '16 Aug 2020 21:43'	System	17 Aug 2020 02:43:08

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 18:01:00

US3252119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 7'	System	11 Aug 2020 18:01:00

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-18T07:34:24', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '1da41061-3c5c-4669-b7c0-fedbed57a4e1'	System	18 Aug 2020 12:34:59
User entered 'None (0)'	System	18 Aug 2020 12:34:59

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-18T07:34:27', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '1da41061-3c5c-4669-b7c0-fedbed57a4e1'	System	18 Aug 2020 12:34:59
User entered 'None (0)'	System	18 Aug 2020 12:34:59

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-18T07:34:32', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '1da41061-3c5c-4669-b7c0-fedbed57a4e1'	System	18 Aug 2020 12:34:59
User entered 'None (0)'	System	18 Aug 2020 12:34:59

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-18T07:34:36', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '1da41061-3c5c-4669-b7c0-fedbed57a4e1'	System	18 Aug 2020 12:34:59
User entered 'None (0)'	System	18 Aug 2020 12:34:59

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-18T07:34:40', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '1da41061-3c5c-4669-b7c0-fedbed57a4e1'	System	18 Aug 2020 12:34:59
User entered 'None (0)'	System	18 Aug 2020 12:34:59

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-18T07:34:42', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '1da41061-3c5c-4669-b7c0-fedbed57a4e1'	System	18 Aug 2020 12:34:59
User entered 'None (0)'	System	18 Aug 2020 12:34:59

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00
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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-18T07:34:55', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '1da41061-3c5c-4669-b7c0-fedbed57a4e1'	System	18 Aug 2020 12:34:59
User entered 'No (N)'	System	18 Aug 2020 12:34:59

US3252119
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-08-18T07:34:57', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '1da41061-3c5c-4669-b7c0-fedbed57a4e1'	System	18 Aug 2020 12:34:59
User entered '18 Aug 2020 07:34'	System	18 Aug 2020 12:34:59

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 18:01:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	20 Aug 2020 20:20:13
	(b) (4)	

US3252119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '19 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:20:13

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:20:13

US3252119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:00

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:20:13

US3252119

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:20:20

US3252119

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered '1'	System	20 Aug 2020 20:20:20

US3252119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	26 Aug 2020 15:54:50
	(b) (4)	

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '25 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	26 Aug 2020 15:54:50

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4) (b) (4)	26 Aug 2020 15:54:50

US3252119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:00

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Shannon Moyer (b) (4) (b) (4)	26 Aug 2020 15:54:50

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	26 Aug 2020 15:54:57

US3252119
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:17:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered '1'	System	26 Aug 2020 15:54:57

Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 21:03:23

Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '01 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 21:03:23

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 21:03:23

US3252119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:00

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 21:03:23

US3252119

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 21:03:29

US3252119

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered '1'	System	02 Sep 2020 21:03:29

US3252119
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:17:00

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:25:23

US3252119
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:17:00

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '8 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:25:23

US3252119

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:25:23

US3252119
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:17:00
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered 'VISIT2'	System	09 Sep 2020 05:25:23

US3252119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:17:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

US3252119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '8 Sep 2020'	Shannon Moyer (b) (4)	09 Sep 2020 05:27:29
	(b) (4)	

US3252119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '13:32' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 21:27:02
User entered '13:31'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered '8 Sep 2020 13:32'	System	09 Sep 2020 21:27:02
User entered '8 Sep 2020 13:31'	System	09 Sep 2020 05:27:29

US3252119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '97.8' F	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

US3252119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

US3252119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:17:00

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '87'	Shannon Moyer (b) (4)	09 Sep 2020 05:27:29
	(b) (4)	

US3252119
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:17:00
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered 'bpm'	System	09 Sep 2020 05:27:29

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:17:00

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '15'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered 'breaths/min'	System	09 Sep 2020 05:27:29

US3252119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '115'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:17:00

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered 'mmHg'	System	09 Sep 2020 05:27:29

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '80'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

US3252119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered 'mmHg'	System	09 Sep 2020 05:27:29

US3252119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

US3252119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '8 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '15:18'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered '8 Sep 2020 15:18'	System	09 Sep 2020 05:27:29

US3252119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '97.8' F	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

US3252119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:17:00

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '82'	Shannon Moyer (b) (4)	09 Sep 2020 05:27:29
	(b) (4)	

US3252119
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:17:00
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered 'bpm'	System	09 Sep 2020 05:27:29

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '15'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

US3252119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered 'breaths/min'	System	09 Sep 2020 05:27:29

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '110'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

FDA-CBER-2022-1614-0714456

US3252119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered 'mmHg'	System	09 Sep 2020 05:27:29

US3252119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '72'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:29

US3252119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered 'mmHg'	System	09 Sep 2020 05:27:29

US3252119

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:00

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis　(b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Shannon Moyer (b) (4)　(b) (4)	09 Sep 2020 05:27:44

US3252119

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:00

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:27:44

US3252119
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:17:00

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 05:28:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 05:28:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:28:00
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 20:13:08
User entered empty.	Joanna Gurrola Mahoney (b) (4)	08 Sep 2020 20:13:08

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Joanna Gurrola Mahoney (b) (4)	08 Sep 2020 20:13:08

US3252119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

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)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Joanna Gurrola Mahoney (b) (4)	08 Sep 2020 20:13:08

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 05:28:00
User entered empty.	System	08 Sep 2020 20:13:08

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '8 Sep 2020'	Joanna Gurrola Mahoney (b) (4)	08 Sep 2020 20:13:08

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:17:00

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '14:41'	Joanna Gurrola Mahoney (b) (4)	08 Sep 2020 20:13:08

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered '8 Sep 2020 14:41'	System	08 Sep 2020 20:13:08

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola Mahoney (b) (4)	08 Sep 2020 20:13:08

US3252119
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:17:00
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered 'ONCE'	System	09 Sep 2020 05:28:00
User entered empty.	System	08 Sep 2020 20:13:08

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:17:00

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 05:28:00
User entered empty.	System	08 Sep 2020 20:13:08

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Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:17:00
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:28:29

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '8 Sep 2020'	Shannon Moyer (b) (4)	09 Sep 2020 05:28:29
	(b) (4)	

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '14:15'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:28:29

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered '8 Sep 2020 14:15'	System	09 Sep 2020 05:28:29

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 16:17:00
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '8 Sep 2020'	Shannon Moyer (b) (4)	09 Sep 2020 05:28:54
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:17:00

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:28:54

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:17:00
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:28:54

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '13:41'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:28:54

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:17:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered '8 Sep 2020 13:41'	System	09 Sep 2020 05:28:54

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:17:00

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:28:54

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:28:54

US3252119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:28:54

US3252119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:17:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered empty.	System	09 Sep 2020 05:28:54

US3252119

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 05:29:00

US3252119
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:17:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered '1'	System	09 Sep 2020 05:29:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T15:21:11', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'd8dea690-95aa-4fdc-9c54-0d0e52610e5a'	System	08 Sep 2020 20:21:29
User entered 'Yes (Y)'	System	08 Sep 2020 20:21:29

US3252119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T15:21:16', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'd8dea690-95aa-4fdc-9c54-0d0e52610e5a'	System	08 Sep 2020 20:21:29
User entered '97.8'	System	08 Sep 2020 20:21:29

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T15:21:21', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'd8dea690-95aa-4fdc-9c54-0d0e52610e5a'	System	08 Sep 2020 20:21:29
User entered 'No (N)'	System	08 Sep 2020 20:21:29

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T15:21:27', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'd8dea690-95aa-4fdc-9c54-0d0e52610e5a'	System	08 Sep 2020 20:21:29
User entered '08 Sep 2020 15:21'	System	08 Sep 2020 20:21:29

US3252119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '08 Sep 2020 15:01'	System	08 Sep 2020 20:13:08

Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '08 Sep 2020 17:31'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T20:11:01', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '12557a42-1812-403a-86fd-38c6318b4a34'	System	09 Sep 2020 01:11:22
User entered 'Yes (Y)'	System	09 Sep 2020 01:11:22

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T20:11:11', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '12557a42-1812-403a-86fd-38c6318b4a34'	System	09 Sep 2020 01:11:22
User entered '97.2'	System	09 Sep 2020 01:11:22

US3252119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T20:11:16', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '12557a42-1812-403a-86fd-38c6318b4a34'	System	09 Sep 2020 01:11:22
User entered 'No (N)'	System	09 Sep 2020 01:11:22

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T20:11:19', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '12557a42-1812-403a-86fd-38c6318b4a34'	System	09 Sep 2020 01:11:22
User entered '08 Sep 2020 20:11'	System	09 Sep 2020 01:11:22

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '08 Sep 2020 18:26'	System	08 Sep 2020 20:13:08

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

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US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 2'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:17:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-09T21:23:31', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'c8fe2d21-078d-4054-ad73-b1285c132561'	System	10 Sep 2020 02:23:53
User entered 'Yes (Y)'	System	10 Sep 2020 02:23:53

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:17:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-09T21:23:41', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'c8fe2d21-078d-4054-ad73-b1285c132561'	System	10 Sep 2020 02:23:53
User entered '97.3'	System	10 Sep 2020 02:23:53

US3252119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-09T21:23:47', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'c8fe2d21-078d-4054-ad73-b1285c132561'	System	10 Sep 2020 02:23:53
User entered 'No (N)'	System	10 Sep 2020 02:23:53

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-09T21:23:50', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'c8fe2d21-078d-4054-ad73-b1285c132561'	System	10 Sep 2020 02:23:53
User entered '09 Sep 2020 21:23'	System	10 Sep 2020 02:23:53

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 3'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:17:00
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-10T22:50:44', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '18616921-ef3d-4395-869d-18e2748f9e43'	System	11 Sep 2020 03:51:12
User entered 'Yes (Y)'	System	11 Sep 2020 03:51:12

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:17:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-10T22:50:53', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '18616921-ef3d-4395-869d-18e2748f9e43'	System	11 Sep 2020 03:51:12
User entered '96.9'	System	11 Sep 2020 03:51:12

US3252119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-10T22:50:58', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '18616921-ef3d-4395-869d-18e2748f9e43'	System	11 Sep 2020 03:51:12
User entered 'No (N)'	System	11 Sep 2020 03:51:12

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-10T22:51:09', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '18616921-ef3d-4395-869d-18e2748f9e43'	System	11 Sep 2020 03:51:12
User entered '10 Sep 2020 22:51'	System	11 Sep 2020 03:51:12

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 20:13:08

US3252119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 4'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:17:00
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:17:00
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:17:00
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:17:00
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:17:00

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

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EAB) (1725)

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PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 20:13:08

Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 5'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:17:00
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:17:00
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:17:00
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:17:00
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 20:13:08

US3252119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 6'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:17:00
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T07:11:58', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '5cf2e095-f561-44f2-bd92-7a53f90f536a'	System	14 Sep 2020 12:12:24
User entered 'Yes (Y)'	System	14 Sep 2020 12:12:24

US3252119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T07:12:14', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '5cf2e095-f561-44f2-bd92-7a53f90f536a'	System	14 Sep 2020 12:12:24
User entered '96.9'	System	14 Sep 2020 12:12:24

US3252119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T07:12:19', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '5cf2e095-f561-44f2-bd92-7a53f90f536a'	System	14 Sep 2020 12:12:24
User entered 'No (N)'	System	14 Sep 2020 12:12:24

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T07:12:22', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '5cf2e095-f561-44f2-bd92-7a53f90f536a'	System	14 Sep 2020 12:12:24
User entered '14 Sep 2020 07:12'	System	14 Sep 2020 12:12:24

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 20:13:08

US3252119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 7'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:17:00
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T20:33:42', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '74c520fd-b551-42e5-b288-f29ce29de66c'	System	15 Sep 2020 01:34:12
User entered 'Yes (Y)'	System	15 Sep 2020 01:34:12

US3252119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T20:34:01', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '74c520fd-b551-42e5-b288-f29ce29de66c'	System	15 Sep 2020 01:34:12
User entered '96.7'	System	15 Sep 2020 01:34:12

US3252119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T20:34:05', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '74c520fd-b551-42e5-b288-f29ce29de66c'	System	15 Sep 2020 01:34:12
User entered 'No (N)'	System	15 Sep 2020 01:34:12

US3252119
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T20:34:10', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '74c520fd-b551-42e5-b288-f29ce29de66c'	System	15 Sep 2020 01:34:12
User entered '14 Sep 2020 20:34'	System	15 Sep 2020 01:34:12

US3252119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 20:13:08

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 20:13:08

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T15:21:34', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'f9ef1547-7341-41e3-9eef-c0837b769e5f'	System	08 Sep 2020 20:22:05
User entered 'None (1)'	System	08 Sep 2020 20:22:05

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T15:21:45', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'f9ef1547-7341-41e3-9eef-c0837b769e5f'	System	08 Sep 2020 20:22:05
User entered 'No (N)'	System	08 Sep 2020 20:22:05

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T15:21:48', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'f9ef1547-7341-41e3-9eef-c0837b769e5f'	System	08 Sep 2020 20:22:05
User entered 'No (N)'	System	08 Sep 2020 20:22:05

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T15:21:58', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'f9ef1547-7341-41e3-9eef-c0837b769e5f'	System	08 Sep 2020 20:22:05
User entered 'None (1)'	System	08 Sep 2020 20:22:05

Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T15:22:01', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'f9ef1547-7341-41e3-9eef-c0837b769e5f'	System	08 Sep 2020 20:22:05
User entered '08 Sep 2020 15:22'	System	08 Sep 2020 20:22:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '08 Sep 2020 15:01'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '08 Sep 2020 17:31'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 20:13:08

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T20:11:29', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'c5b1c6a9-4c18-4841-a34f-8994797bcf79'	System	09 Sep 2020 01:11:49
User entered 'None (1)'	System	09 Sep 2020 01:11:49

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T20:11:33', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'c5b1c6a9-4c18-4841-a34f-8994797bcf79'	System	09 Sep 2020 01:11:49
User entered 'No (N)'	System	09 Sep 2020 01:11:49

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T20:11:38', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'c5b1c6a9-4c18-4841-a34f-8994797bcf79'	System	09 Sep 2020 01:11:49
User entered 'No (N)'	System	09 Sep 2020 01:11:49

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T20:11:43', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'c5b1c6a9-4c18-4841-a34f-8994797bcf79'	System	09 Sep 2020 01:11:49
User entered 'None (1)'	System	09 Sep 2020 01:11:49

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T20:11:45', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'c5b1c6a9-4c18-4841-a34f-8994797bcf79'	System	09 Sep 2020 01:11:49
User entered '08 Sep 2020 20:11'	System	09 Sep 2020 01:11:49

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '08 Sep 2020 18:26'	System	08 Sep 2020 20:13:08

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 2'	System	08 Sep 2020 20:13:08

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-09T21:24:01', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '420d9b62-02b6-4059-9127-84936f362f37'	System	10 Sep 2020 02:24:23
User entered 'None (1)'	System	10 Sep 2020 02:24:23

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-09T21:24:06', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '420d9b62-02b6-4059-9127-84936f362f37'	System	10 Sep 2020 02:24:23
User entered 'No (N)'	System	10 Sep 2020 02:24:23

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-09T21:24:09', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '420d9b62-02b6-4059-9127-84936f362f37'	System	10 Sep 2020 02:24:23
User entered 'No (N)'	System	10 Sep 2020 02:24:23

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-09T21:24:18', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '420d9b62-02b6-4059-9127-84936f362f37'	System	10 Sep 2020 02:24:23
User entered 'None (1)'	System	10 Sep 2020 02:24:23

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-09T21:24:21', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '420d9b62-02b6-4059-9127-84936f362f37'	System	10 Sep 2020 02:24:23
User entered '09 Sep 2020 21:24'	System	10 Sep 2020 02:24:23

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 3'	System	08 Sep 2020 20:13:08

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-10T22:51:22', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'e31fd6c1-1a6d-430c-8883-00daca2f0de5'	System	11 Sep 2020 03:51:40
User entered 'None (1)'	System	11 Sep 2020 03:51:40

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-10T22:51:27', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'e31fd6c1-1a6d-430c-8883-00daca2f0de5'	System	11 Sep 2020 03:51:40
User entered 'No (N)'	System	11 Sep 2020 03:51:40

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:17:00
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-10T22:51:31', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'e31fd6c1-1a6d-430c-8883-00daca2f0de5'	System	11 Sep 2020 03:51:40
User entered 'No (N)'	System	11 Sep 2020 03:51:40

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-10T22:51:35', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'e31fd6c1-1a6d-430c-8883-00daca2f0de5'	System	11 Sep 2020 03:51:40
User entered 'None (1)'	System	11 Sep 2020 03:51:40

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-10T22:51:37', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'e31fd6c1-1a6d-430c-8883-00daca2f0de5'	System	11 Sep 2020 03:51:40
User entered '10 Sep 2020 22:51'	System	11 Sep 2020 03:51:40

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 20:13:08

FDA-CBER-2022-1614-0714577

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 4'	System	08 Sep 2020 20:13:08

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:17:00
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:17:00
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:00

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:17:00
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 07:07:29

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:17:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 5'	System	08 Sep 2020 20:13:08

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:17:00
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:17:00
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:17:00
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:17:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 6'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T07:12:29', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '59f797b8-8655-4976-96f7-6e471dd66c83'	System	14 Sep 2020 12:12:44
User entered 'None (1)'	System	14 Sep 2020 12:12:44

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:17:00
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T07:12:33', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '59f797b8-8655-4976-96f7-6e471dd66c83'	System	14 Sep 2020 12:12:44
User entered 'No (N)'	System	14 Sep 2020 12:12:44

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:17:00
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T07:12:36', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '59f797b8-8655-4976-96f7-6e471dd66c83'	System	14 Sep 2020 12:12:44
User entered 'No (N)'	System	14 Sep 2020 12:12:44

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:17:00
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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T07:12:40', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '59f797b8-8655-4976-96f7-6e471dd66c83'	System	14 Sep 2020 12:12:44
User entered 'None (1)'	System	14 Sep 2020 12:12:44

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T07:12:42', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '59f797b8-8655-4976-96f7-6e471dd66c83'	System	14 Sep 2020 12:12:44
User entered '14 Sep 2020 07:12'	System	14 Sep 2020 12:12:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 20:13:08

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PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 7'	System	08 Sep 2020 20:13:08

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T20:34:16', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '457e9709-bd5e-4c95-aa03-409920792851'	System	15 Sep 2020 01:34:38
User entered 'None (1)'	System	15 Sep 2020 01:34:38

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T20:34:20', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '457e9709-bd5e-4c95-aa03-409920792851'	System	15 Sep 2020 01:34:38
User entered 'No (N)'	System	15 Sep 2020 01:34:38

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T20:34:26', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '457e9709-bd5e-4c95-aa03-409920792851'	System	15 Sep 2020 01:34:38
User entered 'No (N)'	System	15 Sep 2020 01:34:38

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T20:34:34', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '457e9709-bd5e-4c95-aa03-409920792851'	System	15 Sep 2020 01:34:38
User entered 'None (1)'	System	15 Sep 2020 01:34:38

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:17:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T20:34:36', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '457e9709-bd5e-4c95-aa03-409920792851'	System	15 Sep 2020 01:34:38
User entered '14 Sep 2020 20:34'	System	15 Sep 2020 01:34:38

US3252119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T15:22:09', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6f9877ba-3416-4b7e-89a3-acffe1825181'	System	08 Sep 2020 20:22:31
User entered 'None (0)'	System	08 Sep 2020 20:22:31

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T15:22:11', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6f9877ba-3416-4b7e-89a3-acffe1825181'	System	08 Sep 2020 20:22:31
User entered 'None (0)'	System	08 Sep 2020 20:22:31

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T15:22:13', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6f9877ba-3416-4b7e-89a3-acffe1825181'	System	08 Sep 2020 20:22:31
User entered 'None (0)'	System	08 Sep 2020 20:22:31

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T15:22:16', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6f9877ba-3416-4b7e-89a3-acffe1825181'	System	08 Sep 2020 20:22:31
User entered 'None (0)'	System	08 Sep 2020 20:22:31

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T15:22:19', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6f9877ba-3416-4b7e-89a3-acffe1825181'	System	08 Sep 2020 20:22:31
User entered 'None (0)'	System	08 Sep 2020 20:22:31

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T15:22:22', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6f9877ba-3416-4b7e-89a3-acffe1825181'	System	08 Sep 2020 20:22:31
User entered 'None (0)'	System	08 Sep 2020 20:22:31

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T15:22:27', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6f9877ba-3416-4b7e-89a3-acffe1825181'	System	08 Sep 2020 20:22:31
User entered 'No (N)'	System	08 Sep 2020 20:22:31

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T15:22:29', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6f9877ba-3416-4b7e-89a3-acffe1825181'	System	08 Sep 2020 20:22:31
User entered '08 Sep 2020 15:22'	System	08 Sep 2020 20:22:31

US3252119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '08 Sep 2020 15:01'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '08 Sep 2020 17:31'	System	08 Sep 2020 20:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T20:11:53', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '09176707-572f-4c46-b4e9-f211d3c969c7'	System	09 Sep 2020 01:12:39
User entered 'None (0)'	System	09 Sep 2020 01:12:39

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T20:11:58', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '09176707-572f-4c46-b4e9-f211d3c969c7'	System	09 Sep 2020 01:12:39
User entered 'None (0)'	System	09 Sep 2020 01:12:39

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T20:12:04', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '09176707-572f-4c46-b4e9-f211d3c969c7'	System	09 Sep 2020 01:12:39
User entered 'None (0)'	System	09 Sep 2020 01:12:39

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T20:12:09', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '09176707-572f-4c46-b4e9-f211d3c969c7'	System	09 Sep 2020 01:12:39
User entered 'None (0)'	System	09 Sep 2020 01:12:39

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T20:12:13', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '09176707-572f-4c46-b4e9-f211d3c969c7'	System	09 Sep 2020 01:12:39
User entered 'None (0)'	System	09 Sep 2020 01:12:39

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T20:12:25', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '09176707-572f-4c46-b4e9-f211d3c969c7'	System	09 Sep 2020 01:12:39
User entered 'None (0)'	System	09 Sep 2020 01:12:39

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T20:12:34', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '09176707-572f-4c46-b4e9-f211d3c969c7'	System	09 Sep 2020 01:12:39
User entered 'No (N)'	System	09 Sep 2020 01:12:39

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:17:00
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-08T20:12:36', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '09176707-572f-4c46-b4e9-f211d3c969c7'	System	09 Sep 2020 01:12:39
User entered '08 Sep 2020 20:12'	System	09 Sep 2020 01:12:39

US3252119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '08 Sep 2020 18:26'	System	08 Sep 2020 20:13:08

Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:17:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

FDA-CBER-2022-1614-0714636

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 2'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-09T21:24:27', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'e17029b7-d63c-4e32-9b50-d80acaa4a9e5'	System	10 Sep 2020 02:24:54
User entered 'None (0)'	System	10 Sep 2020 02:24:54

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-09T21:24:29', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'e17029b7-d63c-4e32-9b50-d80acaa4a9e5'	System	10 Sep 2020 02:24:54
User entered 'None (0)'	System	10 Sep 2020 02:24:54

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-09T21:24:34', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'e17029b7-d63c-4e32-9b50-d80acaa4a9e5'	System	10 Sep 2020 02:24:54
User entered 'None (0)'	System	10 Sep 2020 02:24:54

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-09T21:24:37', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'e17029b7-d63c-4e32-9b50-d80acaa4a9e5'	System	10 Sep 2020 02:24:54
User entered 'None (0)'	System	10 Sep 2020 02:24:54

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-09T21:24:40', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'e17029b7-d63c-4e32-9b50-d80acaa4a9e5'	System	10 Sep 2020 02:24:54
User entered 'None (0)'	System	10 Sep 2020 02:24:54

US3252119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-09T21:24:42', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'e17029b7-d63c-4e32-9b50-d80acaa4a9e5'	System	10 Sep 2020 02:24:54
User entered 'None (0)'	System	10 Sep 2020 02:24:54

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-09T21:24:49', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'e17029b7-d63c-4e32-9b50-d80acaa4a9e5'	System	10 Sep 2020 02:24:54
User entered 'No (N)'	System	10 Sep 2020 02:24:54

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-09T21:24:51', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'e17029b7-d63c-4e32-9b50-d80acaa4a9e5'	System	10 Sep 2020 02:24:54
User entered '09 Sep 2020 21:24'	System	10 Sep 2020 02:24:54

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 3'	System	08 Sep 2020 20:13:08

US3252119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-10T22:51:43', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6f4236e6-6bd7-4d90-ac4e-e71b4a33f0f8'	System	11 Sep 2020 03:52:08
User entered 'None (0)'	System	11 Sep 2020 03:52:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:17:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-10T22:51:45', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6f4236e6-6bd7-4d90-ac4e-e71b4a33f0f8'	System	11 Sep 2020 03:52:08
User entered 'None (0)'	System	11 Sep 2020 03:52:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:17:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-10T22:51:49', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6f4236e6-6bd7-4d90-ac4e-e71b4a33f0f8'	System	11 Sep 2020 03:52:08
User entered 'None (0)'	System	11 Sep 2020 03:52:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:17:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-10T22:51:52', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6f4236e6-6bd7-4d90-ac4e-e71b4a33f0f8'	System	11 Sep 2020 03:52:08
User entered 'None (0)'	System	11 Sep 2020 03:52:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:17:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-10T22:51:55', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6f4236e6-6bd7-4d90-ac4e-e71b4a33f0f8'	System	11 Sep 2020 03:52:08
User entered 'None (0)'	System	11 Sep 2020 03:52:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:17:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-10T22:51:58', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6f4236e6-6bd7-4d90-ac4e-e71b4a33f0f8'	System	11 Sep 2020 03:52:08
User entered 'None (0)'	System	11 Sep 2020 03:52:08

US3252119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-10T22:52:04', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6f4236e6-6bd7-4d90-ac4e-e71b4a33f0f8'	System	11 Sep 2020 03:52:08
User entered 'No (N)'	System	11 Sep 2020 03:52:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:17:00
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-10T22:52:06', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '6f4236e6-6bd7-4d90-ac4e-e71b4a33f0f8'	System	11 Sep 2020 03:52:08
User entered '10 Sep 2020 22:52'	System	11 Sep 2020 03:52:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 20:13:08

US3252119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 4'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:17:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:17:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:17:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:17:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:17:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:17:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:17:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 20:13:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

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US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 5'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:17:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:17:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:17:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:17:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:17:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:17:00

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 07:07:29

US3252119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 20:13:08

US3252119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 6'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:17:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T07:12:48', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7c9162e7-30f2-43b0-9bef-cfc200214da1'	System	14 Sep 2020 12:13:12
User entered 'None (0)'	System	14 Sep 2020 12:13:12

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:17:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T07:12:50', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7c9162e7-30f2-43b0-9bef-cfc200214da1'	System	14 Sep 2020 12:13:12
User entered 'None (0)'	System	14 Sep 2020 12:13:12

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:17:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T07:12:52', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7c9162e7-30f2-43b0-9bef-cfc200214da1'	System	14 Sep 2020 12:13:12
User entered 'None (0)'	System	14 Sep 2020 12:13:12

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:17:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T07:12:54', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7c9162e7-30f2-43b0-9bef-cfc200214da1'	System	14 Sep 2020 12:13:12
User entered 'None (0)'	System	14 Sep 2020 12:13:12

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:17:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T07:12:57', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7c9162e7-30f2-43b0-9bef-cfc200214da1'	System	14 Sep 2020 12:13:12
User entered 'None (0)'	System	14 Sep 2020 12:13:12

US3252119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T07:13:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7c9162e7-30f2-43b0-9bef-cfc200214da1'	System	14 Sep 2020 12:13:12
User entered 'None (0)'	System	14 Sep 2020 12:13:12

US3252119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T07:13:05', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7c9162e7-30f2-43b0-9bef-cfc200214da1'	System	14 Sep 2020 12:13:12
User entered 'No (N)'	System	14 Sep 2020 12:13:12

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:17:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T07:13:07', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '7c9162e7-30f2-43b0-9bef-cfc200214da1'	System	14 Sep 2020 12:13:12
User entered '14 Sep 2020 07:13'	System	14 Sep 2020 12:13:12

US3252119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:17:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	08 Sep 2020 20:13:08
User entered 'Day 7'	System	08 Sep 2020 20:13:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T20:34:41', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '0a1a073f-3eef-456c-a912-4951e856204a'	System	15 Sep 2020 01:35:08
User entered 'None (0)'	System	15 Sep 2020 01:35:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T20:34:43', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '0a1a073f-3eef-456c-a912-4951e856204a'	System	15 Sep 2020 01:35:08
User entered 'None (0)'	System	15 Sep 2020 01:35:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T20:34:47', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '0a1a073f-3eef-456c-a912-4951e856204a'	System	15 Sep 2020 01:35:08
User entered 'None (0)'	System	15 Sep 2020 01:35:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T20:34:51', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '0a1a073f-3eef-456c-a912-4951e856204a'	System	15 Sep 2020 01:35:08
User entered 'None (0)'	System	15 Sep 2020 01:35:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T20:34:54', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '0a1a073f-3eef-456c-a912-4951e856204a'	System	15 Sep 2020 01:35:08
User entered 'None (0)'	System	15 Sep 2020 01:35:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T20:34:56', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '0a1a073f-3eef-456c-a912-4951e856204a'	System	15 Sep 2020 01:35:08
User entered 'None (0)'	System	15 Sep 2020 01:35:08

US3252119
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:17:00
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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T20:35:04', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '0a1a073f-3eef-456c-a912-4951e856204a'	System	15 Sep 2020 01:35:08
User entered 'No (N)'	System	15 Sep 2020 01:35:08

US3252119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-09-14T20:35:06', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '0a1a073f-3eef-456c-a912-4951e856204a'	System	15 Sep 2020 01:35:08
User entered '14 Sep 2020 20:35'	System	15 Sep 2020 01:35:08

US3252119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 20:13:08

US3252119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 20:13:08

Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	16 Sep 2020 04:17:35

Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '15 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	16 Sep 2020 04:17:35

US3252119
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	16 Sep 2020 04:17:35

US3252119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:00

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Nancy Torrence (b) (4)	16 Sep 2020 04:17:35
	(b) (4)	

US3252119

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	16 Sep 2020 04:17:41

US3252119
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:17:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered '1'	System	16 Sep 2020 04:17:41

US3252119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 04:28:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '24 Sep 2020'	Nancy Torrence (b) (4)	25 Sep 2020 04:28:08
	(b) (4)	

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 04:28:08

US3252119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:00

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 04:28:08

US3252119
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 04:28:10

US3252119
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:17:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered '1'	System	25 Sep 2020 04:28:10

US3252119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	30 Sep 2020 04:58:30

Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '29 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	30 Sep 2020 04:58:30

US3252119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:00

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	30 Sep 2020 04:58:30

Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Nancy Torrence (b) (4) (b) (4)	30 Sep 2020 04:58:30

US3252119

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	30 Sep 2020 04:58:35

US3252119
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:17:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered '1'	System	30 Sep 2020 04:58:35

US3252119
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:17:00

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:01:18

US3252119
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:17:00
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '7 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:01:18

US3252119

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Clinic (Clinic)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:01:18

US3252119
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:17:00
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered 'VISIT3'	System	08 Oct 2020 06:01:18

US3252119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	08 Oct 2020 06:02:10
	(b) (4)	

US3252119
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '7 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:02:10

US3252119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '9:37' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 16:25:45
User entered '9:23'	Nancy Torrence (b) (4)	08 Oct 2020 06:02:10
	(b) (4)	

US3252119
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered '7 Oct 2020 9:37'	System	09 Oct 2020 16:25:45
User entered '7 Oct 2020 9:23'	System	08 Oct 2020 06:02:10

US3252119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:00

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '98.2' F	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:02:10

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Oral (Oral)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:02:10

FDA-CBER-2022-1614-0714730

US3252119
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Nancy Torrence (b) (4)	08 Oct 2020 06:02:10
	(b) (4)	

US3252119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:00

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '94'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:02:10

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered 'bpm'	System	08 Oct 2020 06:02:10

FDA-CBER-2022-1614-0714733

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '15'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:02:10

US3252119
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered 'breaths/min'	System	08 Oct 2020 06:02:10

US3252119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:00

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '116'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:02:10

US3252119
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered 'mmHg'	System	08 Oct 2020 06:02:10

US3252119
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '80'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:02:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered 'mmHg'	System	08 Oct 2020 06:02:10

FDA-CBER-2022-1614-0714739

US3252119
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25

US3252119
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25

US3252119

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:00

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:02:39

Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:17:00

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered empty.	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:02:39

US3252119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:00

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:02:55

US3252119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:00

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 05:28:48
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'It is under unscheduled visit due to 0 quantity of kit type A. As per PPD GSS, we can use kit type UV for backup. US3252119 visit is recorded correctly in EDC.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 17:37:02
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:22:28
User entered '7 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:02:55

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered '9:45'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:02:55

FDA-CBER-2022-1614-0714746

US3252119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered '7 Oct 2020 9:45'	System	08 Oct 2020 06:02:55

US3252119

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:45:38
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:03:02

US3252119
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:17:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:25
User entered '1'	System	08 Oct 2020 06:03:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 64'	System	11 Aug 2020 18:01:00

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-10-14T08:30:05', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8b4f99e0-1491-4cc7-8013-0a18ff24a902'	System	14 Oct 2020 13:31:16
User entered 'No (N)'	System	14 Oct 2020 13:31:16

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-10-14T08:30:49', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8b4f99e0-1491-4cc7-8013-0a18ff24a902'	System	14 Oct 2020 13:31:16
User entered 'Yes (Y)'	System	14 Oct 2020 13:31:16

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Please 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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-10-14T08:30:59', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8b4f99e0-1491-4cc7-8013-0a18ff24a902'	System	14 Oct 2020 13:31:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Oct 2020 13:31:16

US3252119
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-10-14T08:31:06', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8b4f99e0-1491-4cc7-8013-0a18ff24a902'	System	14 Oct 2020 13:31:16
User entered '14 Oct 2020 08:31:06'	System	14 Oct 2020 13:31:16

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 18:01:00

Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 18:01:00

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 71'	System	11 Aug 2020 18:01:00

FDA-CBER-2022-1614-0714757

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-10-20T11:20:27', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8fd7567b-0eaf-4c08-b83f-850b058ca888'	System	20 Oct 2020 16:21:19
User entered 'Yes (Y)'	System	20 Oct 2020 16:21:19

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-10-20T11:20:37', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8fd7567b-0eaf-4c08-b83f-850b058ca888'	System	20 Oct 2020 16:21:19
User entered 'No (N)'	System	20 Oct 2020 16:21:19

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-10-20T11:20:43', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8fd7567b-0eaf-4c08-b83f-850b058ca888'	System	20 Oct 2020 16:21:19
User entered 'No (N)'	System	20 Oct 2020 16:21:19

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-10-20T11:20:51', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8fd7567b-0eaf-4c08-b83f-850b058ca888'	System	20 Oct 2020 16:21:19
User entered 'Yes (Y)'	System	20 Oct 2020 16:21:19

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Please 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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-10-20T11:21:06', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8fd7567b-0eaf-4c08-b83f-850b058ca888'	System	20 Oct 2020 16:21:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Oct 2020 16:21:19

US3252119
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-10-20T11:21:10', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '8fd7567b-0eaf-4c08-b83f-850b058ca888'	System	20 Oct 2020 16:21:19
User entered '20 Oct 2020 11:21:10'	System	20 Oct 2020 16:21:19

US3252119
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 18:01:00

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 78'	System	11 Aug 2020 18:01:00

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-10-25T09:45:10', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '9bd5a87f-8b1d-44d6-aa74-f88b27944570'	System	25 Oct 2020 14:46:31
User entered 'Yes (Y)'	System	25 Oct 2020 14:46:31

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-10-25T09:45:23', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '9bd5a87f-8b1d-44d6-aa74-f88b27944570'	System	25 Oct 2020 14:46:31
User entered 'No (N)'	System	25 Oct 2020 14:46:31

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-10-25T09:45:41', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '9bd5a87f-8b1d-44d6-aa74-f88b27944570'	System	25 Oct 2020 14:46:31
User entered 'No (N)'	System	25 Oct 2020 14:46:31

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-10-25T09:45:51', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '9bd5a87f-8b1d-44d6-aa74-f88b27944570'	System	25 Oct 2020 14:46:31
User entered 'Yes (Y)'	System	25 Oct 2020 14:46:31

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Please 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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-10-25T09:45:58', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '9bd5a87f-8b1d-44d6-aa74-f88b27944570'	System	25 Oct 2020 14:46:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Oct 2020 14:46:31

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-10-25T09:46:02', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '9bd5a87f-8b1d-44d6-aa74-f88b27944570'	System	25 Oct 2020 14:46:31
User entered '25 Oct 2020 09:46:02'	System	25 Oct 2020 14:46:31

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 18:01:00

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 92'	System	11 Aug 2020 18:01:00

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-11-08T05:17:53', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'da2c0e7d-bbae-4901-881f-27812b1ca813'	System	08 Nov 2020 11:18:07
User entered 'No (N)'	System	08 Nov 2020 11:18:07

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-11-08T05:17:59', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'da2c0e7d-bbae-4901-881f-27812b1ca813'	System	08 Nov 2020 11:18:07
User entered 'No (N)'	System	08 Nov 2020 11:18:07

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-11-08T05:18:04', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'da2c0e7d-bbae-4901-881f-27812b1ca813'	System	08 Nov 2020 11:18:07
User entered '08 Nov 2020 05:18:04'	System	08 Nov 2020 11:18:07

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 18:01:00

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered 'Day 99'	System	11 Aug 2020 18:01:00

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-11-17T09:23:25', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '2a76fb38-46ed-43cf-9dbe-35ce1afe8d46'	System	17 Nov 2020 15:23:36
User entered 'No (N)'	System	17 Nov 2020 15:23:36

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-11-17T09:23:29', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '2a76fb38-46ed-43cf-9dbe-35ce1afe8d46'	System	17 Nov 2020 15:23:36
User entered 'No (N)'	System	17 Nov 2020 15:23:36

US3252119
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-11-17T09:23:33', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '2a76fb38-46ed-43cf-9dbe-35ce1afe8d46'	System	17 Nov 2020 15:23:36
User entered '17 Nov 2020 09:23:33'	System	17 Nov 2020 15:23:36

US3252119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 18:01:00

US3252119
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:07:29
Data entry locked.	System	11 Aug 2020 18:01:00
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 18:01:00

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-11-21T21:46:47', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '50e36ceb-e754-406d-85db-69ce0efa24b3'	System	22 Nov 2020 03:46:59
User entered 'No (N)'	System	22 Nov 2020 03:46:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-11-21T21:46:51', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '50e36ceb-e754-406d-85db-69ce0efa24b3'	System	22 Nov 2020 03:46:59
User entered 'No (N)'	System	22 Nov 2020 03:46:59

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-11-21T21:46:55', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '50e36ceb-e754-406d-85db-69ce0efa24b3'	System	22 Nov 2020 03:46:59
User entered '21 Nov 2020 21:46:55'	System	22 Nov 2020 03:46:59

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-11-29T18:16:35', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '9391c62b-98e8-4954-8d1c-c392700019d2'	System	30 Nov 2020 00:16:52
User entered 'No (N)'	System	30 Nov 2020 00:16:52

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-11-29T18:16:40', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '9391c62b-98e8-4954-8d1c-c392700019d2'	System	30 Nov 2020 00:16:52
User entered 'No (N)'	System	30 Nov 2020 00:16:52

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-11-29T18:16:50', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '9391c62b-98e8-4954-8d1c-c392700019d2'	System	30 Nov 2020 00:16:52
User entered '29 Nov 2020 18:16:50'	System	30 Nov 2020 00:16:52

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-12-04T14:12:21', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '57bd515c-295a-4f3c-945d-ba26bc9ecf5d'	System	04 Dec 2020 20:12:38
User entered 'No (N)'	System	04 Dec 2020 20:12:38

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-12-04T14:12:32', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '57bd515c-295a-4f3c-945d-ba26bc9ecf5d'	System	04 Dec 2020 20:12:38
User entered 'No (N)'	System	04 Dec 2020 20:12:38

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-12-04T14:12:36', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '57bd515c-295a-4f3c-945d-ba26bc9ecf5d'	System	04 Dec 2020 20:12:38
User entered '04 Dec 2020 14:12:36'	System	04 Dec 2020 20:12:38

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-12-10T16:13:45', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'd18ebd5f-827c-47dc-9b0f-c0cc62e5ffb7'	System	10 Dec 2020 22:13:55
User entered 'No (N)'	System	10 Dec 2020 22:13:55

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-12-10T16:13:50', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'd18ebd5f-827c-47dc-9b0f-c0cc62e5ffb7'	System	10 Dec 2020 22:13:55
User entered 'No (N)'	System	10 Dec 2020 22:13:55

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-12-10T16:13:53', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'd18ebd5f-827c-47dc-9b0f-c0cc62e5ffb7'	System	10 Dec 2020 22:13:55
User entered '10 Dec 2020 16:13:53'	System	10 Dec 2020 22:13:55

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-12-19T17:19:01', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '461fa589-74d6-4139-ae69-36aa77546432'	System	19 Dec 2020 23:19:11
User entered 'No (N)'	System	19 Dec 2020 23:19:11

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-12-19T17:19:05', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '461fa589-74d6-4139-ae69-36aa77546432'	System	19 Dec 2020 23:19:11
User entered 'No (N)'	System	19 Dec 2020 23:19:11

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-12-19T17:19:08', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '461fa589-74d6-4139-ae69-36aa77546432'	System	19 Dec 2020 23:19:11
User entered '19 Dec 2020 17:19:08'	System	19 Dec 2020 23:19:11

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:53:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-12-25T14:12:13', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '3d4a2305-816e-4406-8fbb-9308c702e706'	System	25 Dec 2020 20:12:25
User entered 'No (N)'	System	25 Dec 2020 20:12:25

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-12-25T14:12:19', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '3d4a2305-816e-4406-8fbb-9308c702e706'	System	25 Dec 2020 20:12:25
User entered 'No (N)'	System	25 Dec 2020 20:12:25

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2020-12-25T14:12:22', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '3d4a2305-816e-4406-8fbb-9308c702e706'	System	25 Dec 2020 20:12:25
User entered '25 Dec 2020 14:12:22'	System	25 Dec 2020 20:12:25

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-01-08T16:52:42', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'f51be88b-1c2a-4336-b115-556d083fdf02'	System	08 Jan 2021 22:52:55
User entered 'No (N)'	System	08 Jan 2021 22:52:55

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-01-08T16:52:47', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'f51be88b-1c2a-4336-b115-556d083fdf02'	System	08 Jan 2021 22:52:55
User entered 'No (N)'	System	08 Jan 2021 22:52:55

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-01-08T16:52:50', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'f51be88b-1c2a-4336-b115-556d083fdf02'	System	08 Jan 2021 22:52:55
User entered '08 Jan 2021 16:52:50'	System	08 Jan 2021 22:52:55

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-01-22T22:39:25', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'ded6c0a4-1769-4d36-95a5-045139c71492'	System	23 Jan 2021 04:39:42
User entered 'No (N)'	System	23 Jan 2021 04:39:42

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-01-22T22:39:30', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'ded6c0a4-1769-4d36-95a5-045139c71492'	System	23 Jan 2021 04:39:42
User entered 'No (N)'	System	23 Jan 2021 04:39:42

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-01-22T22:39:36', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'ded6c0a4-1769-4d36-95a5-045139c71492'	System	23 Jan 2021 04:39:42
User entered '22 Jan 2021 22:39:36'	System	23 Jan 2021 04:39:42

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:53:18

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US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-01-28T16:25:01', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '05b2bd35-5db6-4502-9950-7151817b234e'	System	28 Jan 2021 22:25:10
User entered 'No (N)'	System	28 Jan 2021 22:25:10

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-01-28T16:25:04', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '05b2bd35-5db6-4502-9950-7151817b234e'	System	28 Jan 2021 22:25:10
User entered 'No (N)'	System	28 Jan 2021 22:25:10

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-01-28T16:25:07', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '05b2bd35-5db6-4502-9950-7151817b234e'	System	28 Jan 2021 22:25:10
User entered '28 Jan 2021 16:25:07'	System	28 Jan 2021 22:25:10

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-02-06T22:15:52', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '9a90b1b8-8812-449f-a09d-112056a4cf6a'	System	07 Feb 2021 04:16:06
User entered 'No (N)'	System	07 Feb 2021 04:16:06

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-02-06T22:15:57', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '9a90b1b8-8812-449f-a09d-112056a4cf6a'	System	07 Feb 2021 04:16:06
User entered 'No (N)'	System	07 Feb 2021 04:16:06

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-02-06T22:16:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '9a90b1b8-8812-449f-a09d-112056a4cf6a'	System	07 Feb 2021 04:16:06
User entered '06 Feb 2021 22:16:00'	System	07 Feb 2021 04:16:06

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:53:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-02-11T17:43:57', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '124197d0-f4bd-4930-ace4-1fc357e72cad'	System	11 Feb 2021 23:44:10
User entered 'No (N)'	System	11 Feb 2021 23:44:10

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-02-11T17:44:01', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '124197d0-f4bd-4930-ace4-1fc357e72cad'	System	11 Feb 2021 23:44:10
User entered 'No (N)'	System	11 Feb 2021 23:44:10

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-02-11T17:44:04', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '124197d0-f4bd-4930-ace4-1fc357e72cad'	System	11 Feb 2021 23:44:10
User entered '11 Feb 2021 17:44:04'	System	11 Feb 2021 23:44:10

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-02-20T09:04:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '80d2fd9d-10c5-44aa-b092-a57f833f9663'	System	20 Feb 2021 15:04:12
User entered 'No (N)'	System	20 Feb 2021 15:04:12

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-02-20T09:04:05', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '80d2fd9d-10c5-44aa-b092-a57f833f9663'	System	20 Feb 2021 15:04:12
User entered 'No (N)'	System	20 Feb 2021 15:04:12

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-02-20T09:04:09', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '80d2fd9d-10c5-44aa-b092-a57f833f9663'	System	20 Feb 2021 15:04:12
User entered '20 Feb 2021 09:04:09'	System	20 Feb 2021 15:04:12

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-02-25T11:27:28-06:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'ab3d9403-7cc6-47ce-9682-bd5e95b5b53b'	System	25 Feb 2021 17:28:55
User entered 'No (N)'	System	25 Feb 2021 17:28:55

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-02-25T11:27:35-06:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'ab3d9403-7cc6-47ce-9682-bd5e95b5b53b'	System	25 Feb 2021 17:28:55
User entered 'No (N)'	System	25 Feb 2021 17:28:55

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-02-25T11:27:38-06:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'ab3d9403-7cc6-47ce-9682-bd5e95b5b53b'	System	25 Feb 2021 17:28:55
User entered '25 Feb 2021 17:27:38'	System	25 Feb 2021 17:28:55

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-03-05T14:48:12-06:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'aaccc731-ec11-40db-9474-ed13454db724'	System	05 Mar 2021 23:17:11
User entered 'No (N)'	System	05 Mar 2021 23:17:11

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-03-05T14:48:21-06:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'aaccc731-ec11-40db-9474-ed13454db724'	System	05 Mar 2021 23:17:11
User entered 'No (N)'	System	05 Mar 2021 23:17:11

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-03-05T14:48:26-06:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'aaccc731-ec11-40db-9474-ed13454db724'	System	05 Mar 2021 23:17:11
User entered '05 Mar 2021 14:48:26'	System	05 Mar 2021 23:17:11

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:53:18

FDA-CBER-2022-1614-0714877

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-03-15T10:55:32-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '35b2ca87-09fb-4961-83b6-b1848633429a'	System	15 Mar 2021 15:55:43
User entered 'No (N)'	System	15 Mar 2021 15:55:43

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-03-15T10:55:36-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '35b2ca87-09fb-4961-83b6-b1848633429a'	System	15 Mar 2021 15:55:43
User entered 'No (N)'	System	15 Mar 2021 15:55:43

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-03-15T10:55:39-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '35b2ca87-09fb-4961-83b6-b1848633429a'	System	15 Mar 2021 15:55:43
User entered '15 Mar 2021 10:55:39'	System	15 Mar 2021 15:55:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:53:18

FDA-CBER-2022-1614-0714881

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-03-20T21:29:57-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'e2269109-fb96-46ac-bc5d-0802b831ae66'	System	21 Mar 2021 02:30:13
User entered 'No (N)'	System	21 Mar 2021 02:30:13

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-03-20T21:30:04-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'e2269109-fb96-46ac-bc5d-0802b831ae66'	System	21 Mar 2021 02:30:13
User entered 'No (N)'	System	21 Mar 2021 02:30:13

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-03-20T21:30:07-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'e2269109-fb96-46ac-bc5d-0802b831ae66'	System	21 Mar 2021 02:30:13
User entered '20 Mar 2021 21:30:07'	System	21 Mar 2021 02:30:13

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-03-27T19:29:12-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '0c13393f-1909-495d-b4a8-f55aa5f8852c'	System	28 Mar 2021 00:29:25
User entered 'No (N)'	System	28 Mar 2021 00:29:25

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-03-27T19:29:16-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '0c13393f-1909-495d-b4a8-f55aa5f8852c'	System	28 Mar 2021 00:29:25
User entered 'No (N)'	System	28 Mar 2021 00:29:25

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-03-27T19:29:20-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '0c13393f-1909-495d-b4a8-f55aa5f8852c'	System	28 Mar 2021 00:29:25
User entered '27 Mar 2021 19:29:20'	System	28 Mar 2021 00:29:25

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-04-16T08:57:27-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '0b183479-aee2-4c4d-931b-82298c023269'	System	16 Apr 2021 13:57:41
User entered 'No (N)'	System	16 Apr 2021 13:57:41

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-04-16T08:57:34-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '0b183479-aee2-4c4d-931b-82298c023269'	System	16 Apr 2021 13:57:41
User entered 'No (N)'	System	16 Apr 2021 13:57:41

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-04-16T08:57:37-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '0b183479-aee2-4c4d-931b-82298c023269'	System	16 Apr 2021 13:57:41
User entered '16 Apr 2021 08:57:37'	System	16 Apr 2021 13:57:41

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-04-22T16:13:18-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '19348dff-73ec-4dce-8ced-ec9cd639891c'	System	22 Apr 2021 21:13:34
User entered 'No (N)'	System	22 Apr 2021 21:13:34

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-04-22T16:13:25-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '19348dff-73ec-4dce-8ced-ec9cd639891c'	System	22 Apr 2021 21:13:34
User entered 'No (N)'	System	22 Apr 2021 21:13:34

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-04-22T16:13:29-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '19348dff-73ec-4dce-8ced-ec9cd639891c'	System	22 Apr 2021 21:13:34
User entered '22 Apr 2021 16:13:29'	System	22 Apr 2021 21:13:34

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:53:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-05-03T12:06:14-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '835c75e3-cd56-4122-bb7c-54664659b8b6'	System	03 May 2021 17:11:58
User entered 'Yes (Y)'	System	03 May 2021 17:11:58

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Have you been exposed to someone with 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-05-03T12:06:21-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '835c75e3-cd56-4122-bb7c-54664659b8b6'	System	03 May 2021 17:11:58
User entered 'No (N)'	System	03 May 2021 17:11:58

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-05-03T12:06:29-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '835c75e3-cd56-4122-bb7c-54664659b8b6'	System	03 May 2021 17:11:58
User entered 'No (N)'	System	03 May 2021 17:11:58

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-05-03T12:06:43-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '835c75e3-cd56-4122-bb7c-54664659b8b6'	System	03 May 2021 17:11:58
User entered 'Yes (Y)'	System	03 May 2021 17:11:58

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Please 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 (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-05-03T12:07:00-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '835c75e3-cd56-4122-bb7c-54664659b8b6'	System	03 May 2021 17:11:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 May 2021 17:11:58

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-05-03T12:07:13-05:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: '835c75e3-cd56-4122-bb7c-54664659b8b6'	System	03 May 2021 17:11:58
User entered '03 May 2021 12:07:13'	System	03 May 2021 17:11:58

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:53:18

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US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:53:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:53:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:53:18

FDA-CBER-2022-1614-0714934

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:53:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:53:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:53:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:53:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:53:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:53:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:53:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:53:18

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US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:53:18

FDA-CBER-2022-1614-0715032

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:53:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:53:18

FDA-CBER-2022-1614-0715034

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:53:18

FDA-CBER-2022-1614-0715039

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:53:18

FDA-CBER-2022-1614-0715040

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:53:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:53:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:53:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:53:18

FDA-CBER-2022-1614-0715055

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:53:18

FDA-CBER-2022-1614-0715066

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:53:18

FDA-CBER-2022-1614-0715069

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:53:18

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:53:18

FDA-CBER-2022-1614-0715084

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:53:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:53:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:53:18

FDA-CBER-2022-1614-0715105

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:53:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:53:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:53:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:53:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:53:18

US3252119
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:17:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:53:18

US3252119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:18
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:53:18

US3252119

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:17:00

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-02-27T16:25:29-06:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'ba0dac32-f870-4254-a38d-2087431794db'	System	27 Feb 2021 22:25:42
User entered 'No (N)'	System	27 Feb 2021 22:25:42

US3252119

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:17:00

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E27100D5-CA50-4EBF-A4E5-C31B6EDB5681)', Time: '2021-02-27T16:25:36-06:00', User OID: 'PatientReportedOutcome (US3252119)', ODM File OID: 'ba0dac32-f870-4254-a38d-2087431794db'	System	27 Feb 2021 22:25:42
User entered '27 Feb 2021 22:25:36'	System	27 Feb 2021 22:25:42

US3252119
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 02:35:40

FDA-CBER-2022-1614-0715152

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '3 Nov 2020'	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 02:35:40

US3252119

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:00

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 02:35:40

US3252119
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered empty.	Nancy Torrence (b) (4)	04 Nov 2020 02:35:40
	(b) (4)	

US3252119

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 02:35:55

US3252119
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:17:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:42:19
User entered '1'	System	04 Nov 2020 02:35:55

US3252119
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Dec 2020 02:35:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '7 Dec 2020'	Shannon Moyer (b) (4)	08 Dec 2020 02:35:31
	(b) (4)	

US3252119
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	08 Dec 2020 02:35:31
	(b) (4)	

US3252119
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Dec 2020 02:35:31

US3252119

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Dec 2020 02:35:35

US3252119
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:17:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User entered '1'	System	08 Dec 2020 02:35:35

US3252119
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 06:58:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Jan 2021 06:58:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	07 Jan 2021 06:58:45
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 06:58:35
User entered empty.	Shannon Moyer (b) (4) (b) (4)	07 Jan 2021 06:58:35

US3252119

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '6 Jan 2021'	Shannon Moyer (b) (4) (b) (4)	07 Jan 2021 06:58:35

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4) (b) (4)	07 Jan 2021 06:58:35

US3252119
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered empty.	Shannon Moyer (b) (4)	07 Jan 2021 06:58:35
	(b) (4)	

US3252119

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	07 Jan 2021 06:58:40
	(b) (4)	

US3252119
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:17:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User entered '1'	System	07 Jan 2021 06:58:40

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 02:27:48

FDA-CBER-2022-1614-0715170

US3252119

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '8 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 02:27:48

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Feb 2021 02:27:48

US3252119
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 02:27:48

US3252119

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 02:27:52

US3252119
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:17:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User entered '1'	System	09 Feb 2021 02:27:52

US3252119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:17:00

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 03:18:06

US3252119
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:17:00

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered '19 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 03:18:06

US3252119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Mar 2021 03:18:06

Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:17:00
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User entered 'VISIT4'	System	22 Mar 2021 03:18:06

US3252119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 06:49:45

US3252119
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 06:49:45

US3252119
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 06:49:45

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User entered empty.	System	29 Mar 2021 06:49:45

Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 06:49:45

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US3252119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:00

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 06:49:45

US3252119
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 06:49:45

US3252119
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 06:49:45

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User entered empty.	System	29 Mar 2021 06:49:45

US3252119
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 06:49:45

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User entered empty.	System	29 Mar 2021 06:49:45

US3252119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:00

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 06:49:45

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User entered empty.	System	29 Mar 2021 06:49:45

FDA-CBER-2022-1614-0715192

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 06:49:45

FDA-CBER-2022-1614-0715193

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User entered empty.	System	29 Mar 2021 06:49:45

FDA-CBER-2022-1614-0715194

US3252119
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14

Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:17:00
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 03:18:23

FDA-CBER-2022-1614-0715197

Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:17:00
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 03:18:23

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:00

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 03:18:39

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered '19 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 03:18:39

FDA-CBER-2022-1614-0715200

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered '09:25'	(b) (4), (b) (6)	22 Mar 2021 03:18:39

US3252119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User entered '19 Mar 2021 09:25'	System	22 Mar 2021 03:18:39

US3252119

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 03:18:46

US3252119
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:17:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:13:14
User entered '1'	System	22 Mar 2021 03:18:46

US3252119

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

Form: Visit Date

Generated On: 09 Jun 2021 16:17:00

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:36:21

US3252119

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

Form: Visit Date

Generated On: 09 Jun 2021 16:17:00

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '22 Jan 2021'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:36:21

US3252119

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

Form: Visit Date

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:36:21

US3252119
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:17:00
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'UNBLND_DECIDE'	System	23 Jan 2021 04:36:21

US3252119

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '22 Jan 2021'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:36:35

US3252119

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:46:46

US3252119

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:00

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:36:35

US3252119

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:00

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:46:46

US3252119

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:00

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '22 Jan 2021'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:36:35

US3252119

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:00

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Placebo (Placebo)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:36:35

US3252119

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:00

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Placebo (Placebo)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:36:35

US3252119

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:00

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Placebo (Placebo)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:36:35

US3252119

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:00

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:36:35

US3252119

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:00

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered '1'	System	23 Jan 2021 04:36:35

US3252119
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:17:00
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered '1'	System	23 Jan 2021 04:36:35

US3252119

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:17:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:17:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:17:00

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered empty.	System	23 Jan 2021 04:38:39
DataPoint set to visible.	System	23 Jan 2021 04:36:35

US3252119

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:17:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:17:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:17:00

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered empty.	System	23 Jan 2021 04:38:39
DataPoint set to visible.	System	23 Jan 2021 04:36:35

US3252119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '22 Jan 2021'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '09:21'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered '22 Jan 2021 09:21'	System	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '98.5' F	Shannon Moyer (b) (4)	23 Jan 2021 04:38:39
	(b) (4)	

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	23 Jan 2021 04:38:39
	(b) (4)	

US3252119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered empty.	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '90'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'bpm'	System	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '16'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'breaths/min'	System	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '113'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'mmHg'	System	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '80'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'mmHg'	System	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:17:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	23 Jan 2021 04:38:39
	(b) (4)	

US3252119

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:17:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:17:00

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered empty.	System	23 Jan 2021 04:38:39
DataPoint set to visible.	System	23 Jan 2021 04:36:35

US3252119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '22 Jan 2021'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '10:12'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered '22 Jan 2021 10:12'	System	23 Jan 2021 04:38:39

US3252119
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:17:00
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '98.2' F	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

FDA-CBER-2022-1614-0715250

US3252119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered empty.	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '86'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'bpm'	System	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '14'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:17:00

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'breaths/min'	System	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '120'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'mmHg'	System	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '81'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:38:39

US3252119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'mmHg'	System	23 Jan 2021 04:38:39

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:00

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 05:38:07

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered empty.	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 05:38:07

FDA-CBER-2022-1614-0715262

US3252119

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

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 05:38:23

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered empty.	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 05:38:23

FDA-CBER-2022-1614-0715264

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

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

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 08:01:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered empty.	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 05:38:23

US3252119

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

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:04
User entered 'mRNA-1273'	System	23 Jan 2021 05:38:23
DataPoint set to visible.	System	23 Jan 2021 04:36:35

US3252119

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

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:04
User closed query 'Per CDMRQ: please review date in IRT and update accordingly' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 06:57:21
Query 'Per CDMRQ: please review date in IRT and update accordingly' answered with 'the date entered in EDC is correct and DCFs will be submitted to Endpoint' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 05:14:49
User opened query 'Per CDMRQ: please review date in IRT and update accordingly' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 15:25:12
User closed query 'Per CDM, per sponsor review: Per IRT, Subject had Open Label Day1 Treatment on 19FEB2021. Please review and reconcile.' (Site from DM).		15 Apr 2021 15:25:12
Query 'Per CDM, per sponsor review: Per IRT, Subject had Open Label Day1 Treatment on 19FEB2021. Please review and reconcile.' answered with "per source the OL-day1 was performed on 22 jan 2021, while OL-day29 was performed on 19 feb 2021." (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:42:02
User opened query 'Per CDM, per sponsor review: Per IRT, Subject had Open Label Day1 Treatment on 19FEB2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 08:50:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '22 Jan 2021'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 05:38:23

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

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '09:39'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 05:38:23

Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:17:00

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:04
User entered '22 Jan 2021 09:39'	System	23 Jan 2021 05:38:23

US3252119

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

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Left Arm (LEFT ARM)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 05:38:23

US3252119

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

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:04
User entered 'ONCE'	System	23 Jan 2021 05:38:23

US3252119

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

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:04
User entered 'INTRAMUSCULAR'	System	23 Jan 2021 05:38:23

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 05:38:37

US3252119

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:00

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '22 Jan 2021'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 05:38:37

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '09:20'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 05:38:37

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered '22 Jan 2021 09:20'	System	23 Jan 2021 05:38:37

US3252119

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:17:00

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 05:38:45

US3252119

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:17:00

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '22 Jan 2021'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 05:38:45

US3252119

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '09:20'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 05:38:45

US3252119

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:17:00

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered '22 Jan 2021 09:20'	System	23 Jan 2021 05:38:45

US3252119

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

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 05:38:50

US3252119

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

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered '1'	System	23 Jan 2021 05:38:50

US3252119
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis　(b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	01 Feb 2021 05:18:53

FDA-CBER-2022-1614-0715283

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '29 Jan 2021'	Joanna Gurrola Mahoney (b) (4)	01 Feb 2021 05:18:53

Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Contact Made (CONTACT MADE)'	Joanna Gurrola Mahoney (b) (4)	01 Feb 2021 05:18:53

US3252119
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered empty.	Joanna Gurrola Mahoney (b) (4)	01 Feb 2021 05:18:53

US3252119

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	01 Feb 2021 05:18:58

US3252119
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:17:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered '1'	System	01 Feb 2021 05:18:58

US3252119
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:17:00
OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered '1'	System	01 Feb 2021 05:18:58
DataPoint set to visible.	System	01 Feb 2021 05:18:58

US3252119
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:17:00

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Feb 2021 02:21:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '19 Feb 2021'	(b) (4), (b) (6)	20 Feb 2021 02:21:43

FDA-CBER-2022-1614-0715291

US3252119

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Feb 2021 02:21:43

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'OLD29'	System	20 Feb 2021 02:21:43

FDA-CBER-2022-1614-0715293

US3252119
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:17:00
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Feb 2021 02:22:53

US3252119
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:17:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Feb 2021 02:22:53

US3252119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '19 Feb 2021'	(b) (4), (b) (6)	20 Feb 2021 02:22:53

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '16:26'	(b) (4), (b) (6)	20 Feb 2021 02:22:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered '19 Feb 2021 16:26'	System	20 Feb 2021 02:22:53

FDA-CBER-2022-1614-0715298

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '98.7' F	(b) (4), (b) (6)	20 Feb 2021 02:22:53

FDA-CBER-2022-1614-0715299

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Feb 2021 02:22:53

US3252119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered empty.	(b) (4), (b) (6)	20 Feb 2021 02:22:53

US3252119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '99'	(b) (4), (b) (6)	20 Feb 2021 02:22:53

US3252119
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:17:00
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'bpm'	System	20 Feb 2021 02:22:53

US3252119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '16'	(b) (4), (b) (6)	20 Feb 2021 02:22:53

US3252119
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:17:00
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'breaths/min'	System	20 Feb 2021 02:22:53

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '134'	(b) (4), (b) (6)	20 Feb 2021 02:22:53

FDA-CBER-2022-1614-0715306

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'mmHg'	System	20 Feb 2021 02:22:53

US3252119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:00

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '81'	(b) (4), (b) (6)	20 Feb 2021 02:22:53

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'mmHg'	System	20 Feb 2021 02:22:53

US3252119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Feb 2021 02:22:53

US3252119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Feb 2021 02:22:53

US3252119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '19 Feb 2021'	(b) (4), (b) (6)	20 Feb 2021 02:22:53

US3252119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '17:35'	(b) (4), (b) (6)	20 Feb 2021 02:22:53

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered '19 Feb 2021 17:35'	System	20 Feb 2021 02:22:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '98.2' F	(b) (4), (b) (6)	20 Feb 2021 02:22:53

US3252119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Feb 2021 02:22:53

US3252119
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:17:00
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered empty.	(b) (4), (b) (6)	20 Feb 2021 02:22:53

US3252119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '128'	(b) (4), (b) (6)	20 Feb 2021 02:22:53

US3252119
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:17:00
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'bpm'	System	20 Feb 2021 02:22:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '16'	(b) (4), (b) (6)	20 Feb 2021 02:22:53

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'breaths/min'	System	20 Feb 2021 02:22:53

US3252119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:00

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '115'	(b) (4), (b) (6)	20 Feb 2021 02:22:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'mmHg'	System	20 Feb 2021 02:22:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '78'	(b) (4), (b) (6)	20 Feb 2021 02:22:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'mmHg'	System	20 Feb 2021 02:22:53

FDA-CBER-2022-1614-0715325

US3252119

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:00

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'No (N)'	(b) (4), (b) (6)	20 Feb 2021 02:22:58

US3252119

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:00

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered empty.	(b) (4), (b) (6)	20 Feb 2021 02:22:58

US3252119
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:17:00

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:41:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Feb 2021 02:26:54

US3252119
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:17:00
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:41:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered empty.	(b) (4), (b) (6)	20 Feb 2021 02:26:54

US3252119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:41:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered empty.	(b) (4), (b) (6)	20 Feb 2021 02:26:54

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'mRNA-1273'	System	20 Feb 2021 02:26:54
DataPoint set to visible.	System	01 Feb 2021 05:18:58

Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:17:00

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:41:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '19 Feb 2021'	(b) (4), (b) (6)	20 Feb 2021 02:26:54

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:41:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '16:57'	(b) (4), (b) (6)	20 Feb 2021 02:26:54

FDA-CBER-2022-1614-0715333

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered '19 Feb 2021 16:57'	System	20 Feb 2021 02:26:54

US3252119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:17:00

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:41:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	20 Feb 2021 02:26:54

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:41:05
User entered 'ONCE'	System	20 Feb 2021 02:26:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'INTRAMUSCULAR'	System	20 Feb 2021 02:26:54

FDA-CBER-2022-1614-0715337

US3252119

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Feb 2021 02:27:05

US3252119

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered '1'	System	20 Feb 2021 02:27:05

US3252119
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 04:51:41

US3252119

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered '26 Feb 2021'	(b) (4), (b) (6)	01 Mar 2021 04:51:41

US3252119
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Mar 2021 04:51:41

US3252119
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:17:00
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 04:51:41

US3252119

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 04:51:47

US3252119
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:17:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered '1'	System	01 Mar 2021 04:51:47

US3252119
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:17:00

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 02:41:52

US3252119
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:17:00

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered '19 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 02:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Mar 2021 02:41:52

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'OLD57'	System	22 Mar 2021 02:41:52

US3252119
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 02:43:01

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered '19 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 02:43:01

US3252119
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered '09:11'	(b) (4), (b) (6)	22 Mar 2021 02:43:01

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered '19 Mar 2021 09:11'	System	22 Mar 2021 02:43:01

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US3252119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:00

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered '97.9' F	(b) (4), (b) (6)	22 Mar 2021 02:43:01

US3252119
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Mar 2021 02:43:01

US3252119
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 02:43:01

US3252119
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered '87'	(b) (4), (b) (6)	22 Mar 2021 02:43:01

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'bpm'	System	22 Mar 2021 02:43:01

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Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered '16'	(b) (4), (b) (6)	22 Mar 2021 02:43:01

Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'breaths/min'	System	22 Mar 2021 02:43:01

US3252119
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered '124'	(b) (4), (b) (6)	22 Mar 2021 02:43:01

US3252119
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'mmHg'	System	22 Mar 2021 02:43:01

US3252119
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered '80'	(b) (4), (b) (6)	22 Mar 2021 02:43:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered 'mmHg'	System	22 Mar 2021 02:43:01

US3252119
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57

US3252119
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:17:00

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57

US3252119

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:00

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 02:43:10

US3252119

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:00

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 02:43:10

Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:17:00

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 02:43:16

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 02:43:16

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US3252119

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 02:43:16

Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:17:00
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:56:57
User entered empty.	System	22 Mar 2021 02:43:16

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US3252119
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 16:17:00

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:40:39
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 14:10:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:25:04
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:31:14

US3252119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

AEID

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 14:11:05
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:35:56
User entered 'USA-US108-2020-mRNA-1273-P301000006'	System	21 Oct 2020 20:35:40
User entered 'New'	(b) (4), (b) (6)	21 Oct 2020 20:35:40

US3252119
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:17:00
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:10:20
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 22:28:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 22:28:30
Data point term sent to Coder	System	20 Oct 2020 22:27:27
User entered 'Myocardial Infarction'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:17:00

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:10:22
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:10:42
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

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US3252119
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:17:00
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:11:01
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

US3252119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▨ (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6) ▨	12 Nov 2020 15:11:05
User entered '14 Oct 2020'	Joanna Gurrola Mahoney (b) (4) ▨	20 Oct 2020 22:27:08

US3252119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:30:00
User closed query 'Per source, start time is 20:35. Please review and reconcile. ' (Site from CRA).		24 Nov 2020 18:03:18
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Nov 2020 15:43:14
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 15:43:14
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Nov 2020 15:39:01
User entered '20:35' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 15:39:01
Query 'Per source, start time is 20:35. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Shannon Moyer (b) (4) (b) (4)	23 Nov 2020 07:48:34
User opened query 'Per source, start time is 20:35. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 14:12:41
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	17 Nov 2020 05:55:50
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	17 Nov 2020 05:55:50
User closed query 'Per source, start time is 16:00 Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:42:01
User entered '20:35' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	13 Nov 2020 20:35:28
Query 'Per source, start time is 16:00 Please review and reconcile. ' answered with 'source updated' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	13 Nov 2020 20:34:21
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	13 Nov 2020 20:26:24
User entered '17:15' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	13 Nov 2020 20:26:24
User opened query 'Per source, start time is 16:00 Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 15:11:21
User entered empty.	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 15:43:14
User entered '14 Oct 2020 20:35'	System	24 Nov 2020 15:39:01
User entered empty.	System	17 Nov 2020 05:55:50
User entered '14 Oct 2020 20:35'	System	13 Nov 2020 20:35:28
User entered '14 Oct 2020 17:15'	System	13 Nov 2020 20:26:24
User entered empty.	System	20 Oct 2020 22:27:08

FDA-CBER-2022-1614-0715381

US3252119
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:17:00
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:11:26
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

US3252119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▓(b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	▓(b) (4), (b) (6)▓	12 Nov 2020 15:11:30
User entered '20 Oct 2020'	Joanna Gurrola Mahoney ▓(b) (4)▓	20 Oct 2020 22:27:08

US3252119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 14:13:06
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	17 Nov 2020 05:55:50
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	17 Nov 2020 05:55:50
User entered '00:00' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	13 Nov 2020 20:34:09
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	13 Nov 2020 20:31:36
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	13 Nov 2020 20:31:36
User entered '16:00' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	13 Nov 2020 20:31:36
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:11:32
User entered empty.	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

US3252119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 05:55:50
User entered '20 Oct 2020 00:00'	System	13 Nov 2020 20:34:09
User entered '20 Oct 2020 16:00'	System	13 Nov 2020 20:31:36
User entered empty.	System	20 Oct 2020 22:27:08

US3252119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

Severity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:11:48
User entered 'Grade 4 (Grade 4)'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

US3252119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:11:51
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

US3252119
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:17:00
Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 23:09:28
DataPoint Un-verified.		20 Nov 2020 23:08:32
DataPoint Verified.		20 Nov 2020 23:08:28
User entered '0'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:12:07
User entered '1'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

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US3252119
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:17:00
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 23:09:26
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	20 Oct 2020 22:27:35
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	20 Oct 2020 22:27:35
User entered '1' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:35
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	20 Oct 2020 22:27:08
User entered '0'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

US3252119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:13:46
User entered '14 Oct 2020'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

US3252119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:12:52
User entered '20 Oct 2020'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

US3252119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ███ (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6) ███	23 Nov 2020 23:09:43
User entered 'Yes (Y)'	Joanna Gurrola Mahoney ███ (b) (4) ███	20 Oct 2020 22:27:08

US3252119
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:17:00
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 23:09:41
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 14:38:00
User entered '3' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	13 Nov 2020 20:31:36
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered with 'waiting to receive medical records ' (Site from System).	Xavier Morales (b) (4) (b) (4)	23 Oct 2020 15:40:40
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	20 Oct 2020 22:27:35
User entered empty.	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 23:13:58
User entered '0'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▓(b) (4)▓	05 Mar 2021 20:13:47
DataPoint Verified.	▓(b) (4), (b) (6)▓	23 Nov 2020 23:13:59
User entered '0'	Joanna Gurrola Mahoney ▓(b) (4)▓	20 Oct 2020 22:27:08

US3252119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 23:14:01
User entered '0'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

US3252119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 23:12:22
User entered 'Not Related (NOT RELATED)'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

US3252119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 23:12:23
User entered 'Not Related (NOT RELATED)'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

US3252119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User closed query 'PV Query: Please update the action taken to "not applicable" as both study drug doses were given prior to event onset.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 18:51:04
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 23:11:47
Query 'PV Query: Please update the action taken to "not applicable" as both study drug doses were given prior to event onset.' answered with 'updated' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:50:19
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:50:11
User opened query 'PV Query: Please update the action taken to "not applicable" as both study drug doses were given prior to event onset.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 16:58:34
User entered 'None (NONE)'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

US3252119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

None

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:14:07
User entered '0'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:17:00
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User closed query 'Per DM CLR - RQ: Site's response noted. However, there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 16:01:01
Query 'Per DM CLR - RQ: Site's response noted. However, there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'all medications have been input from the AE. However not all medications were given during this time were for the AE but also for other things such as his diabetes or even vaccines. ' (Site from DM).	Xavier Morales (b) (4) (b) (4)	23 Dec 2020 19:08:53
User opened query 'Per DM CLR - RQ: Site's response noted. However, there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 03:37:07
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 03:37:07
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:14:10
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'UPDATED' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:18:16
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 04:17:49

Concomitant Medication

Audit	User	Time (GMT)
User entered '1'	Joanna Gurrola Mahoney	20 Oct 2020 22:27:08
	(b) (4)	

US3252119
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:17:00
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 13:40:20
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:14:22
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'UPDATED' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:18:24
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 04:17:56
User entered '1'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:14:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:14:27
User entered empty.	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

FDA-CBER-2022-1614-0715406

US3252119
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:17:00
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
User closed query 'PV Query: Please send labs and EKG with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information has been sent.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 15:32:25
Query 'PV Query: Please send labs and EKG with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information has been sent.' answered with 'information has been sent. ' (Site from Safety).	mathew maran (b) (4) (b) (4)	01 Mar 2021 10:15:11
User opened query 'PV Query: Please send labs and EKG with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information has been sent.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 19:29:53
User closed query 'PV Query: Please send labs and EKG 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)	05 Feb 2021 18:40:07
Query 'PV Query: Please send labs and EKG with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. ' answered with 'task sent to Source' (Site from Safety).	Shannon Moyer (b) (4) (b) (4)	04 Feb 2021 06:21:08
User opened query 'PV Query: Please send labs and EKG 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)	29 Dec 2020 19:10:30
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. cardiac biomarkers, EKG, coronary angiography, etc). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 21:37:27
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. cardiac biomarkers, EKG, coronary angiography, etc). Please include units and reference ranges if applicable.' answered with 'labs and EKG has been uploaded onto source ' (Site from Safety).	Xavier Morales (b) (4) (b) (4)	23 Dec 2020 19:03:51

US3252119
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:17:00
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: When did the subject start experiencing symptom of chest pain? SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please confirm If the subject started experiencing chest pain on 14 Oct 2020 (reported onset date of event and admission date). If not, please update so. ' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 18:01:52
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)	07 Dec 2020 18:01:47
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)	07 Dec 2020 18:01:23
Query 'PV Query: When did the subject start experiencing symptom of chest pain? SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please confirm If the subject started experiencing chest pain on 14 Oct 2020 (reported onset date of event and admission date). If not, please update so. ' answered with 'Patient started experiencing symptoms on 14-OCT-2020.' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	04 Dec 2020 22:00:03
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 'Performed left heart catherization, coronary angiography, and left ventriculogram. Performed PCI to the circumflex and and left PDA. ' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	04 Dec 2020 21:58:18

US3252119
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:17:00
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 'Per the medical records, no covid-19 test were done so we have no results.' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	04 Dec 2020 21:22:26
User opened query 'PV Query: When did the subject start experiencing symptom of chest pain? SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please confirm If the subject started experiencing chest pain on 14 Oct 2020 (reported onset date of event and admission date). If not, please update so. ' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 16:53:30
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:14:55
User closed query 'Safety Medical Query: Please provide the subject's presenting signs/symptoms.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 18:58:28
Query 'Safety Medical Query: Please provide the subject's presenting signs/symptoms.' answered with 'Chest pains' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 16:03:12
User opened query 'Safety Medical Query: Please provide the subject's presenting signs/symptoms.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 14:47:59
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)	29 Oct 2020 14:47:50
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. cardiac biomarkers, EKG, coronary angiography, etc). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 14:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

Narrative

Audit	User	Time (GMT)
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)	29 Oct 2020 14:47:36
User entered 'Patient called us to notify us that he suffered a myocardial infarction, treated with medication and a revascularization procedure, we will update the chart when we receive the hospital discharge documentation.'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 22:27:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 22:27:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 22:27:08

US3252119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:00

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 22:27:08

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:40:39
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:15:34
User closed query 'Per ETRTR: Please add Medication dosed for SAE "Myocardial Infarction", thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 20:55:49
Query 'Per ETRTR: Please add Medication dosed for SAE "Myocardial Infarction", thanks.' answered with 'waiting on medical records from hospital' (Site from CRA).	Xavier Morales (b) (4) (b) (4)	27 Oct 2020 13:25:26
User opened query 'Per ETRTR: Please add Medication dosed for SAE "Myocardial Infarction", thanks.' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 21:00:04
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:31:37

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:19:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 01:03:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 01:03:11
Data point term sent to Coder	System	12 Aug 2020 14:33:10
User entered 'Victoza Injection pen'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:32:33

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:19:26
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:32:33

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:19:27
User entered 'Type II Diabetes'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:32:33

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:19:32
User entered '1.8'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:32:33

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:19:33
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:32:33

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:19:35
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:32:33

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:19:38
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:32:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:19:42
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:32:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:19:45
User entered 'Subcutaneous (SUBCUTANEOUS)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:32:33

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:19:48
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:32:33

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:20:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:17:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 14:32:33
User entered 'UN UNK 2016'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:32:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:20:08
User entered '0'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:32:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:20:14
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:32:33

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:20:17
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:32:33

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:20:23
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:32:33

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:17:00
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 14:32:33

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 14:32:33

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 14:32:33

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:42:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:42:15
Data point term sent to Coder	System	12 Aug 2020 14:41:31
User entered 'Lantus'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:41:19

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:11
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:41:19

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:14
User entered 'Type II Diabetes'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:41:19

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:16
User closed query 'Per DM CLR: Please review the recorded dose as it appear as the dosage formulation rather than the actual dose. Please update to record the actual dose administered as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 17:35:17
Query 'Per DM CLR: Please review the recorded dose as it appear as the dosage formulation rather than the actual dose. Please update to record the actual dose administered as appropriate. Otherwise, clarify. ' answered with 'Corrected' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	16 Sep 2020 21:44:18
User entered '100' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	16 Sep 2020 21:44:10
User opened query 'Per DM CLR: Please review the recorded dose as it appear as the dosage formulation rather than the actual dose. Please update to record the actual dose administered as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 07:11:19
User entered '100units/mL'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:41:19

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:18
User entered 'Other (OTHER)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	16 Sep 2020 21:44:10
User entered 'IU (IU)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:41:19

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:17:00
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:19
User entered 'units/ml' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	16 Sep 2020 21:44:10
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:41:19

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:22
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:41:19

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:27
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:41:19

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:25
User entered 'Subcutaneous (SUBCUTANEOUS)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:41:19

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:28
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:41:19

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:31
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:17:15
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 14:41:19
User entered 'UN UNK 2018'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:41:19

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:32
User entered '0'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:41:19

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:35
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:41:19

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:36
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:41:19

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:41
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:41:19

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 14:41:19

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 14:41:19

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 14:41:19

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:43:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:43:08
Data point term sent to Coder	System	12 Aug 2020 14:42:32
User entered 'simvastatin'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:42:09

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:51
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:42:09

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:53
User entered 'Hyperlipidemia'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:42:09

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:55
User entered '20'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:42:09

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:57
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:42:09

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:17:00
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:22:59
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:42:09

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:23:01
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:42:09

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:23:03
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:42:09

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:23:05
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:42:09

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:23:06
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:42:09

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:23:46
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:17:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 14:42:09
User entered 'UN UNK 2016'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:42:09

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:23:48
User entered '0'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:42:09

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:23:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:42:09

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:23:55
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:42:09

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:23:56
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:42:09

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 14:42:09

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 14:42:09

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 14:42:09

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:45:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:45:12
Data point term sent to Coder	System	12 Aug 2020 14:43:33
User entered 'Lisinopril'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:43:25

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:07
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:43:25

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:08
User entered 'Hypertension'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:43:25

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:11
User entered '2.5'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:43:25

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:12
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:43:25

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US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:14
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:43:25

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:16
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:43:25

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:18
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:43:25

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:20
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:43:25

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:21
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:43:25

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:23
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:17:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 14:43:25
User entered 'UN UNK 2016'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:43:25

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:25
User entered '0'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:43:25

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:28
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:43:25

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:29
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:43:25

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:31
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:43:25

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 14:43:25

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 14:43:25

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 14:43:25

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: METRONIDAZOL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 17:08:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 17:08:55
Data point term sent to Coder	System	14 Nov 2020 17:08:31
Coding entries removed.	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 17:07:44
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: METRONIDAZOL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 12:58:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 12:58:21
Data point term sent to Coder	System	04 Nov 2020 12:57:08
Coding entries removed.	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 12:56:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: METRONIDAZOL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 00:12:42

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US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

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 Sep 2020 00:12:42
Data point term sent to Coder	System	23 Sep 2020 18:26:55
Coding entries removed.	Xavier Morales (b) (4) (b) (4)	23 Sep 2020 18:26:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: METRONIDAZOL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 13:11:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 13:11:22
Data point term sent to Coder	System	12 Aug 2020 14:46:39
User entered 'Metronidazol'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:45:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:42
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:45:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:44
User closed query 'Per CDM REQUERY: Please review Indication and please update to specify which foot (e.g. left or right or bilateral feet) have infection. Please update and reconcile with MH eCRF so there would be an appropriate' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 16:29:58
Query 'Per CDM REQUERY: Please review Indication and please update to specify which foot (e.g. left or right or bilateral feet) have infection. Please update and reconcile with MH eCRF so there would be an appropriate' answered with 'Updated and reconciled.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 17:08:01
User entered 'left FOOT INFECTION' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 17:07:44
User opened query 'Per CDM REQUERY: Please review Indication and please update to specify which foot (e.g. left or right or bilateral feet) have infection. Please update and reconcile with MH eCRF so there would be an appropriate' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 22:25:50
User entered 'FOOT INFECTION' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 12:56:58
User closed query 'Per DM CLR: Please review Indication and please update to specify which foot (e.g. left or right or bilateral feet) have infection. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:12:55
Query 'Per DM CLR: Please review Indication and please update to specify which foot (e.g. left or right or bilateral feet) have infection. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. ' answered with 'has been updated' (Site from DM).	Xavier Morales (b) (4) (b) (4)	23 Sep 2020 18:27:12
User entered 'LEFT FOOT INFECTION' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	23 Sep 2020 18:26:00

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review Indication and please update to specify which foot (e.g. left or right or bilateral feet) have infection. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 07:59:15
User entered 'Foot infection'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:45:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:49
User entered '500'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:45:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:51
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:45:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:55
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:45:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:57
User entered 'twice daily (BID)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:45:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:24:59
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:45:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:01
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:45:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:04
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:45:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:17:31
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 14:45:41
User entered 'UN Apr 2020'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:45:41

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:08
User entered '0'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:45:41

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US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:10
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:45:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:12
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	23 Sep 2020 18:28:29
User entered '11 Aug 2020' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	23 Sep 2020 18:28:29
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	12 Aug 2020 14:45:41
User entered '16 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:45:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:14
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:45:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User entered '2'	System	12 Aug 2020 14:45:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User entered '1'	System	12 Aug 2020 14:45:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:40:35
User entered '804 (804)'	System	12 Aug 2020 14:45:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:01
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:23
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: CEFDINIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 08:21:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 08:21:17
Data point term sent to Coder	System	12 Aug 2020 14:46:40
User entered 'Cedinir'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:46:30

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:01
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:25
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:46:30

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:01
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:27
User entered 'Antibiotics for foot infection'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:46:30

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:01
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:29
User entered '300'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:46:30

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:01
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:31
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:46:30

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:01
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:33
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:46:30

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:01
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:35
User entered 'twice daily (BID)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:46:30

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:01
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:37
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:46:30

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:01
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:38
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:46:30

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:01
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:41
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:46:30

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:01
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:43
User entered '04 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:46:30

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:01
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:45
User entered '0'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:46:30

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:01
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:46
User entered 'No (N)' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 12:58:48
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:46:30

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:01
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:48
User entered '15 Sep 2020' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 12:58:48
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:46:30

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:01
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:25:51
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:46:30

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:01
User entered '2'	System	12 Aug 2020 14:46:30

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:01
User entered '1'	System	12 Aug 2020 14:46:30

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:01
User entered '804 (804)'	System	12 Aug 2020 14:46:30

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:26:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 09:52:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 09:52:07
Data point term sent to Coder	System	25 Nov 2020 09:51:01
User entered 'Aspirin'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:50:54

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:26:01
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:50:54

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:26:03
User entered 'General Health'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:50:54

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:26:05
User entered '81'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:50:54

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:26:07
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:50:54

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:26:08
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:50:54

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:26:10
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:50:54

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:26:12
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:50:54

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:26:14
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:50:54

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:26:16
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:50:54

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:26:20
User entered '12 Jun 2019'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:50:54

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:26:22
User entered '0'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:50:54

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:26:24
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:50:54

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:26:26
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:50:54

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:26:29
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:50:54

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 09:50:54

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 09:50:54

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Nov 2020 09:50:54

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User closed query 'Per DM CLR: Con Med ATORVASTATIN CALCIUM was added/changed on 15 OCT 2019. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 15:43:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Feb 2021 05:33:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Feb 2021 05:33:57
Data point term sent to Coder	System	15 Feb 2021 05:33:18
Coding entries removed.	mathew maran (b) (4) (b) (4)	15 Feb 2021 05:32:09
Query 'Per DM CLR: Con Med ATORVASTATIN CALCIUM was added/changed on 15 OCT 2019. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' answered with 'is part of the medication given at hospital for his MI, all of these medications were given during that time and for different reasons related to his MI' (Site from DM).	mathew maran (b) (4) (b) (4)	15 Feb 2021 05:32:02
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:26:39

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Con Med ATORVASTATIN CALCIUM was added/changed on 15 OCT 2019. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:25:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:15:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:15:14
Data point term sent to Coder	System	25 Nov 2020 09:53:02
User entered 'Atorvastatin Calcium'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:52:22

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:26:43
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:52:22

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:56:24
User closed query 'Please correct spelling of Hyperlipidemia.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 17:56:23
Query 'Please correct spelling of Hyperlipidemia.' answered with 'updated thanks' (Site from CRA).	mathew maran (b) (4) (b) (4)	15 Feb 2021 05:32:18
DataPoint Un-verified.	mathew maran (b) (4) (b) (4)	15 Feb 2021 05:32:09
User entered 'Hyperlipidemia' reason for change: Data Entry Error	mathew maran (b) (4) (b) (4)	15 Feb 2021 05:32:09
User opened query 'Please correct spelling of Hyperlipidemia.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 16:27:29
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:26:44
User entered 'Hyperlipidaemia'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:52:22

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:27:33
User entered '40'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:52:22

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:27:35
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:52:22

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:27:37
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:52:22

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:27:38
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:52:22

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:27:40
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:52:22

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:27:44
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:52:22

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:27:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:52:22

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:27:47
User entered '15 Oct 2019'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:52:22

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:27:48
User entered '0'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:52:22

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:27:50
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:52:22

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:27:51
User entered '20 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:52:22

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:27:55
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:52:22

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:35
User entered '1'	System	25 Nov 2020 09:52:22

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:35
User entered '1'	System	25 Nov 2020 09:52:22

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:35
User entered '804 (804)'	System	25 Nov 2020 09:52:22

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:28:07
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 16:28:04
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:05:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 09:55:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 09:55:15
Data point term sent to Coder	System	25 Nov 2020 09:54:02
User entered 'Famotidine'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:53:53

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:05:38
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:53:53

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 15:43:42
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' answered with 'is part of the medication given at hospital for his MI, all of these medications were given during that time and for different reasons related to his MI' (Site from DM).	mathew maran (b) (4) (b) (4)	15 Feb 2021 05:32:52
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:26:28
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:07:00
User entered 'Gastroesophageal reflux disease'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:53:53

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:07:11
User entered '20'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:53:53

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:07:12
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:53:53

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:17:00
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:07:15
User entered empty.	Shannon Moyer (b) (4)	25 Nov 2020 09:53:53
	(b) (4)	

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US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:07:18
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:53:53

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:07:19
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:53:53

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:07:21
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:53:53

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:07:23
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:53:53

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:07:29
User entered '15 Oct 2019'	Shannon Moyer (b) (4)	25 Nov 2020 09:53:53
	(b) (4)	

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:07:30
User entered '0'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:53:53

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:07:32
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:53:53

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:07:33
User entered '20 Oct 2020'	Shannon Moyer (b) (4)	25 Nov 2020 09:53:53
	(b) (4)	

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:07:37
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:53:53

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:59
User entered '1'	System	25 Nov 2020 09:53:53

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:59
User entered '1'	System	25 Nov 2020 09:53:53

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:59
User entered '804 (804)'	System	25 Nov 2020 09:53:53

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:10:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:19:07
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 10:19:07
Data point term sent to Coder	System	25 Nov 2020 09:55:02
User entered 'Zolpidem Tartrate'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:54:55

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:10:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:54:55

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
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 if appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 15:43:55
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 if appropriate.' answered with 'is part of the medication given at hospital for his MI, all of these medications were given during that time and for different reasons related to his MI' (Site from DM).	mathew maran (b) (4) (b) (4)	15 Feb 2021 05:31:34
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 if appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:29:53
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:10:48
User entered 'Nausea'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:54:55

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:10:54
User entered '5'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:54:55

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US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:10:55
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:54:55

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:10:57
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:54:55

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:10:59
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:54:55

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:11:01
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:54:55

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:11:03
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:54:55

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:11:05
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:54:55

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:28:45
User entered '15 Oct 2019'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:54:55

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:28:47
User entered '0'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:54:55

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:11:08
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:54:55

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:11:16
User entered '20 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:54:55

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:11:14
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:54:55

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:25
User entered '1'	System	25 Nov 2020 09:54:55

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:25
User entered '1'	System	25 Nov 2020 09:54:55

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:25
User entered '804 (804)'	System	25 Nov 2020 09:54:55

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:55
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User closed query 'Per DM CLR: Con Med INSULIN HUMAN REGULAR was added/changed on 15 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 15:44:10
Query 'Per DM CLR: Con Med INSULIN HUMAN REGULAR was added/changed on 15 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' answered with 'this was given during hospital stay to manage his diabetes' (Site from DM).	mathew maran (b) (4) (b) (4)	15 Feb 2021 05:30:21
User opened query 'Per DM CLR: Con Med INSULIN HUMAN REGULAR was added/changed on 15 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:30:14
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:28:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN, PRODUCTSYNONYM: INSULIN, REGULAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:20:07
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 10:20:07
Data point term sent to Coder	System	25 Nov 2020 09:57:03
User entered 'Insulin Human Regular'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:56:40

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:55
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:28:32
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:56:40

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:55
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:28:34
User entered 'Type 2 Diabetes'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:56:40

FDA-CBER-2022-1614-0715600

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:55
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:32:27
User closed query 'Per CDM: Please provide the actual dose received by the patient instead of Sliding scale, please review the Dose fields and update appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 15:07:23
Query 'Per CDM: Please provide the actual dose received by the patient instead of Sliding scale, please review the Dose fields and update appropriate, else clarify.' answered with 'Per medical records they state a sliding scale for the dose for the administration of Insulin Human Regular. ' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	04 Dec 2020 22:14:34
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	04 Dec 2020 06:49:13
User entered 'SLIDING SCALE' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	04 Dec 2020 06:49:13
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:28:36
User opened query 'Per CDM: Please provide the actual dose received by the patient instead of Sliding scale, please review the Dose fields and update appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 10:28:23
User entered '"SLIDING SCALE"'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:56:40

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:55
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:11:26
User entered 'Other (OTHER)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:56:40

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:17:00
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:55
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:32:30
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	04 Dec 2020 06:49:13
User entered 'SLIDING SCALE' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	04 Dec 2020 06:49:13
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:11:28
User entered '"SLIDING SCALE"'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:56:40

FDA-CBER-2022-1614-0715603

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:55
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:11:30
User entered 'as needed (PRN)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:56:40

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:17:00
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:55
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:11:34
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:56:40

FDA-CBER-2022-1614-0715605

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:55
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:11:37
User entered 'Subcutaneous (SUBCUTANEOUS)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:56:40

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:55
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:11:40
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:56:40

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:55
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:11:43
User entered '15 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:56:40

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:55
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:11:46
User entered '0'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:56:40

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:55
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:11:47
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:56:40

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:55
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:11:49
User entered '20 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:56:40

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:55
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:11:50
User entered 'No (N)'	Shannon Moyer (b) (4)	25 Nov 2020 09:56:40
	(b) (4)	

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:55
User entered empty.	System	25 Nov 2020 09:56:40

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:55
User entered empty.	System	25 Nov 2020 09:56:40

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:42:55
User entered empty.	System	25 Nov 2020 09:56:40

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:19
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:12:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: MUPIROCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:18:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:18:05
Data point term sent to Coder	System	25 Nov 2020 09:59:03
User entered 'mupirocin'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:58:23

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:19
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:12:55
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:58:23

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:19
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:12:56
User entered 'Prophylaxis for MRSA'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:58:23

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:19
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:13:00
User entered '1'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:58:23

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:19
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:13:02
User entered 'Other (OTHER)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:58:23

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:17:00
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:19
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:13:05
User entered 'Application'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:58:23

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:19
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:13:07
User entered 'twice daily (BID)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:58:23

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:19
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:13:09
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:58:23

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:19
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:13:11
User entered 'Nasal (NASAL)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:58:23

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:19
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:13:35
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:58:23

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:19
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:13:36
User entered '15 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:58:23

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:19
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:13:38
User entered '0'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:58:23

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:19
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:13:39
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:58:23

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:19
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:13:41
User entered '20 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:58:23

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:19
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:13:42
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:58:23

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:19
User entered '2'	System	25 Nov 2020 09:58:23

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:19
User entered '1'	System	25 Nov 2020 09:58:23

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:19
User entered '804 (804)'	System	25 Nov 2020 09:58:23

FDA-CBER-2022-1614-0715633

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:14:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:19:07
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 10:19:07
Data point term sent to Coder	System	25 Nov 2020 10:00:04
User entered 'Ticagrelor'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:59:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:14:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:59:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:28:32
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' answered with 'this was given at the hospital during the AE of the Myocardial Infarction so all this medications are related to that same AE and were all given as PROPHYLAXIS to prevent' (Site from DM).	mathew maran (b) (4) (b) (4)	10 Feb 2021 03:56:23
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:30:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:14:11
User entered 'acute coronary syndrome'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:59:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:14:13
User entered '90'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:59:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▓(b) (4)▓	05 Apr 2021 19:48:17
DataPoint Verified.	▓(b) (4), (b) (6)▓	03 Dec 2020 17:14:14
User entered 'mg (mg)'	Shannon Moyer ▓(b) (4)▓ ▓(b) (4)▓	25 Nov 2020 09:59:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:14:16
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:59:51

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:14:19
User entered 'twice daily (BID)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:59:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:14:21
User entered empty.	Shannon Moyer (b) (4)	25 Nov 2020 09:59:51
	(b) (4)	

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:14:23
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	25 Nov 2020 09:59:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:14:25
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:59:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:14:27
User entered '15 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:59:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:14:49
User entered '0'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:59:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:14:50
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:59:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:14:54
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:59:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:14:56
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:59:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	25 Nov 2020 09:59:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 09:59:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Nov 2020 09:59:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
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)	10 Feb 2021 03:55:42
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 Feb 2021 03:55:42
Data point term sent to Coder	System	10 Feb 2021 03:54:18
Coding entries removed.	mathew maran (b) (4) (b) (4)	10 Feb 2021 03:53:38
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:09
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)	25 Nov 2020 10:03:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:03:12
Data point term sent to Coder	System	25 Nov 2020 10:02:05
User entered 'ACETAMINOPHEN'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:01:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:10
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:01:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:48:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User closed query 'Per CDM: Response to previous query noted. Please update 'indication' as per your response and ensure to reconcile Con Med and AE during this timeframe as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 09:22:04
Query 'Per CDM: Response to previous query noted. Please update 'indication' as per your response and ensure to reconcile Con Med and AE during this timeframe as appropriate else clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 03:09:52
User opened query 'Per CDM: Response to previous query noted. Please update 'indication' as per your response and ensure to reconcile Con Med and AE during this timeframe as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 12:11:08
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)	15 Mar 2021 12:11:08
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 'Medications taken during the time frame of 15-OCT-202 to 20-OCT-2020 were taken at the hospital due to AE of myocardial infarction. All of these medications were due for different reasons such as prophylaxis indications or as maintenance of current medical conditions.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 05:42:17

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:17:00
Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:58:42
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of Pain. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 11:32:41
Query 'Per DM CLR: Please update the indication to reflect the location/type of Pain. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'updated' (Site from DM).	mathew maran (b) (4) (b) (4)	10 Feb 2021 03:53:44
DataPoint Un-verified.	mathew maran (b) (4) (b) (4)	10 Feb 2021 03:53:38
User entered 'Injection site pain' reason for change: Data Entry Error	mathew maran (b) (4) (b) (4)	10 Feb 2021 03:53:38
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of Pain. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:31:00
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:12
User entered 'Pain'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:01:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:36
User entered '650'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:01:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:37
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:01:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:39
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:01:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:40
User entered 'as needed (PRN)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:01:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:42
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:01:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:44
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:01:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:46
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:01:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:48
User entered '15 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:01:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:50
User entered '0'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:01:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:52
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:01:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:53
User entered '20 Oct 2020'	Shannon Moyer (b) (4)	25 Nov 2020 10:01:51
	(b) (4)	

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:40
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:54
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:01:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:40
User entered empty.	System	25 Nov 2020 10:01:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:40
User entered empty.	System	25 Nov 2020 10:01:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:43:40
User entered empty.	System	25 Nov 2020 10:01:51

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:16:44
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 WATER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:16:15
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 10:16:15
Data point term sent to Coder	System	25 Nov 2020 10:04:05
User entered 'Dextrose/Water'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:03:48

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:16:48
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	25 Nov 2020 10:03:48
	(b) (4)	

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:16:50
User entered 'Dehydration'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:03:48

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:16:52
User entered '25'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:03:48

FDA-CBER-2022-1614-0715674

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:36
User entered 'mL (mL)'	Shannon Moyer (b) (4)	25 Nov 2020 10:03:48
	(b) (4)	

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:17:00
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:37
User entered empty.	Shannon Moyer (b) (4)	25 Nov 2020 10:03:48
	(b) (4)	

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:39
User entered 'as needed (PRN)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:03:48

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:40
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:03:48

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:41
User entered 'Intravenous (INTRAVENOUS)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:03:48

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:43
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:03:48

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:44
User entered '15 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:03:48

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:46
User entered '0'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:03:48

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:47
User entered 'No (N)'	Shannon Moyer (b) (4)	25 Nov 2020 10:03:48
	(b) (4)	

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:48
User entered '20 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:03:48

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:14
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:50
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:03:48

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:14
User entered empty.	System	25 Nov 2020 10:03:48

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:14
User entered empty.	System	25 Nov 2020 10:03:48

FDA-CBER-2022-1614-0715687

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:14
User entered empty.	System	25 Nov 2020 10:03:48

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:43
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:04
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PANCREATIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, PRODUCT: GLUCAGON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:17:16
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 10:17:16
Data point term sent to Coder	System	25 Nov 2020 10:06:06
User entered 'glucagon'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:05:07

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:43
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:05
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:05:07

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:43
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User closed query 'Per CDM: Response does not satisfy query. Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:58:16
Query 'Per CDM: Response does not satisfy query. Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' answered with 'as subject is stopped medication no AE/MH required' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 03:58:55
User opened query 'Per CDM: Response does not satisfy query. Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 10:35:49
User closed query 'Per CDM: Response noted "Updated". However update is not obvious please provide location of update such as log line number.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 10:35:49
Query 'Per CDM: Response noted "Updated". However update is not obvious please provide location of update such as log line number.' answered with 'this was given during the time period of the AE' (Site from DM).	mathew maran (b) (4) (b) (4)	15 Feb 2021 05:33:30
User opened query 'Per CDM: Response noted "Updated". However update is not obvious please provide location of update such as log line number.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:37:47

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:37:47
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' answered with ' this was given during the time period of the AE' (Site from DM).	mathew maran (b) (4) (b) (4)	10 Feb 2021 03:55:27
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:31:25
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:06
User entered 'Hypoglycaemia'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:05:07

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:43
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:08
User entered '1'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:05:07

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:43
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:11
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:05:07

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US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:17:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:43
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:13
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:05:07

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:43
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:14
User entered 'as needed (PRN)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:05:07

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:17:00
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:43
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:17
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:05:07

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:43
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:16
User entered 'Intravenous (INTRAVENOUS)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:05:07

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:43
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:19
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:05:07

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:43
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:24
User entered '15 Oct 2020'	Shannon Moyer (b) (4)	25 Nov 2020 10:05:07
	(b) (4)	

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US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:43
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:25
User entered '0'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:05:07

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:43
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:35
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:05:07

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:43
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:37
User entered '20 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:05:07

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:43
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:39
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:05:07

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:43
User entered empty.	System	25 Nov 2020 10:05:07

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:43
User entered empty.	System	25 Nov 2020 10:05:07

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:44:43
User entered empty.	System	25 Nov 2020 10:05:07

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:08:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:08:05
Data point term sent to Coder	System	25 Nov 2020 10:07:06
User entered 'Ondansetron'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:06:24

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:51
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:06:24

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 15:44:36
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' answered with 'this was given during the time period of the AE' (Site from DM).	mathew maran (b) (4) (b) (4)	15 Feb 2021 05:34:02
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:31:49
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:54
User entered 'Nausea'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:06:24

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:56
User entered '4'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:06:24

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:57
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:06:24

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:17:00
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:59
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:06:24

FDA-CBER-2022-1614-0715713

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:42:00
User entered 'as needed (PRN)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:06:24

FDA-CBER-2022-1614-0715714

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:17:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:42:02
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:06:24

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:42:04
User entered 'Intravenous (INTRAVENOUS)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:06:24

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:17:00
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:42:06
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:06:24

FDA-CBER-2022-1614-0715717

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:42:07
User entered '15 Oct 2020'	Shannon Moyer (b) (4)	25 Nov 2020 10:06:24
	(b) (4)	

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:42:09
User entered '0'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:06:24

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:42:10
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:06:24

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:42:11
User entered '20 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:06:24

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:42:13
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:06:24

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:11
User entered empty.	System	25 Nov 2020 10:06:24

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:11
User entered empty.	System	25 Nov 2020 10:06:24

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:11
User entered empty.	System	25 Nov 2020 10:06:24

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:42:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:09:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:09:07
Data point term sent to Coder	System	25 Nov 2020 10:08:07
User entered 'Influenza Vaccine'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:07:32

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:42:24
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:07:32

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:42:27
User entered 'General Health'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:07:32

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:33:41
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	04 Dec 2020 14:00:08
User entered '180' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	04 Dec 2020 14:00:08
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:42:30
User entered '60'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:07:32

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:56:37
User closed query 'Per source, mcg is listed as the dose unit. Please verify and update EDC accordingly. (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 17:56:35
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 04:20:44
Query 'Per source, mcg is listed as the dose unit. Please verify and update EDC accordingly.' answered with 'per query updated' (Site from CRA).	mathew maran (b) (4) (b) (4)	15 Feb 2021 05:34:50
User entered 'Other (OTHER)' reason for change: Data Entry Error	mathew maran (b) (4) (b) (4)	15 Feb 2021 05:34:34
User opened query 'Per source, mcg is listed as the dose unit. Please verify and update EDC accordingly. (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 16:34:08
User closed query 'Per CDM: Please review "Other Unit" - 'MCG' is available in the listed options in Dose Unit field (ug). Please review and select "ug" from the list of drop-down options. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 12:36:47
Query 'Per CDM: Please review "Other Unit" - 'MCG' is available in the listed options in Dose Unit field (ug). Please review and select "ug" from the list of drop-down options. Update eCRF as appropriate. ' answered with 'Dosage updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	04 Dec 2020 14:00:48
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	04 Dec 2020 14:00:29
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	04 Dec 2020 14:00:08
User entered 'IU (IU)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	04 Dec 2020 14:00:08
User opened query 'Per CDM: Please review "Other Unit" - 'MCG' is available in the listed options in Dose Unit field (ug). Please review and select "ug" from the list of drop-down options. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 11:17:51

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:07:32

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:17:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:56:38
User closed query 'Per DM CLR: Please review and verify if the UNIT can be appropriately recorded as ug as it is one of the pre-listed options under UNIT. If yes, please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 08:15:23
Query 'Per DM CLR: Please review and verify if the UNIT can be appropriately recorded as ug as it is one of the pre-listed options under UNIT. If yes, please update accordingly. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 04:21:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 04:20:44
User opened query 'Per DM CLR: Please review and verify if the UNIT can be appropriately recorded as ug as it is one of the pre-listed options under UNIT. If yes, please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:59:40
DataPoint Un-verified.	mathew maran (b) (4) (b) (4)	15 Feb 2021 05:34:34
User entered 'mcg' reason for change: Data Entry Error	mathew maran (b) (4) (b) (4)	15 Feb 2021 05:34:34
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:34:10
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	04 Dec 2020 14:00:29
User entered 'MCG'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:07:32

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:42:39
User entered 'once (ONCE)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:07:32

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:17:00
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:33
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:07:32

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:35
User entered 'Intramuscular (INTRAMUSCULAR)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:07:32

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:38
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:07:32

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:40
User entered '15 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:07:32

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:41
User entered '0'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:07:32

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:43
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:07:32

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:44
User entered '15 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:07:32

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:46
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:07:32

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:51
User entered empty.	System	25 Nov 2020 10:07:32

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:51
User entered empty.	System	25 Nov 2020 10:07:32

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:45:51
User entered empty.	System	25 Nov 2020 10:07:32

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:11:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:11:10
Data point term sent to Coder	System	25 Nov 2020 10:10:07
User entered 'Pneumococcal Vaccine'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:09:29

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:29
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:09:29

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:30
User entered 'General Health'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:09:29

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:32
User entered '0.5'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:09:29

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:34
User entered 'mL (mL)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:09:29

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:17:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:35
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:09:29

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:37
User entered 'once (ONCE)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:09:29

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:17:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:39
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:09:29

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:42
User entered 'Intramuscular (INTRAMUSCULAR)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:09:29

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:44
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:09:29

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:46
User entered '15 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:09:29

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:47
User entered '0'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:09:29

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:49
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:09:29

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:50
User entered '15 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:09:29

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:52
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:09:29

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:25
User entered empty.	System	25 Nov 2020 10:09:29

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:25
User entered empty.	System	25 Nov 2020 10:09:29

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:25
User entered empty.	System	25 Nov 2020 10:09:29

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:45:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE HYDROCHLORIDE, PRODUCTSYNONYM: AMIODARONE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:12:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:12:11
Data point term sent to Coder	System	25 Nov 2020 10:11:08
User entered 'Amiodarone HCl'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:10:43

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User closed query 'Per DM CLR: Prophylaxis=yes. Please review if this should be changed to NO as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 08:11:09
Query 'Per DM CLR: Prophylaxis=yes. Please review if this should be changed to NO as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 04:21:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 04:21:36
User opened query 'Per DM CLR: Prophylaxis=yes. Please review if this should be changed to NO as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:59:07
DataPoint Un-verified.	mathew maran (b) (4) (b) (4)	10 Feb 2021 03:57:01
User entered 'Yes (Y)' reason for change: Data Entry Error	mathew maran (b) (4) (b) (4)	10 Feb 2021 03:57:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:02
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:10:43

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:39:20
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' answered with 'this was given at the hospital during the AE of the Myocardial Infarction so all this medications are related to that same AE and were all given as PROPHYLAXIS to prevent' (Site from DM).	mathew maran (b) (4) (b) (4)	10 Feb 2021 03:56:48
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:32:04
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:04
User entered 'acute coronary syndrome'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:10:43

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:06
User entered '100'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:10:43

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:50:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 10:37:35
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 02:39:47
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 02:39:41
User entered 'Other (OTHER)' reason for change: Data Entry Error		11 Mar 2021 02:39:41
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).		03 Mar 2021 01:59:18
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:09
User entered 'mL (mL)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:10:43

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:17:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:50:37
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 02:39:41
User entered 'mg/ml' reason for change: Data Entry Error		11 Mar 2021 02:39:41
DataPoint Verified.		03 Dec 2020 17:46:10
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:10:43

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:13
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	01 Dec 2020 13:29:04
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	01 Dec 2020 13:29:04
User entered 'once daily (QD)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	01 Dec 2020 13:29:04
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	25 Nov 2020 10:11:31
User entered 'once (ONCE)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:11:31
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	25 Nov 2020 10:11:02
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	25 Nov 2020 10:11:02
User entered 'twice daily (BID)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:11:02
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	25 Nov 2020 10:10:43
User entered 'once (ONCE)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:10:43

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:17:00
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:18
User entered empty.	Shannon Moyer (b) (4)	25 Nov 2020 10:10:43
	(b) (4)	

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:19
User entered 'Intravenous (INTRAVENOUS)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:10:43

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:20
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:10:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:48:29
User entered '15 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:10:43

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:48:30
User entered '0'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:10:43

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:17:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:48:31
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:10:43

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:48:33
User entered '20 Oct 2020'	Shannon Moyer (b) (4)	25 Nov 2020 10:10:43
	(b) (4)	

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:48:34
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:10:43

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:17:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:59
User entered '1'	System	01 Dec 2020 13:29:04
User entered empty.	System	25 Nov 2020 10:11:31
User entered '2'	System	25 Nov 2020 10:11:02
User entered empty.	System	25 Nov 2020 10:10:43

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:59
User entered '1'	System	01 Dec 2020 13:29:04
User entered empty.	System	25 Nov 2020 10:11:31
User entered '1'	System	25 Nov 2020 10:11:02
User entered empty.	System	25 Nov 2020 10:10:43

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:46:59
User entered '804 (804)'	System	01 Dec 2020 13:29:04
User entered empty.	System	25 Nov 2020 10:11:31
User entered '804 (804)'	System	25 Nov 2020 10:11:02
User entered empty.	System	25 Nov 2020 10:10:43

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:17:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:49:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 10:16:15
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 10:16:15
Data point term sent to Coder	System	25 Nov 2020 10:13:08
User entered 'carvedilol'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:12:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:17:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:49:43
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	25 Nov 2020 10:12:41
	(b) (4)	

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:49:45
User entered 'Prophylaxis for heart failure'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:12:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:17:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	27 Dec 2020 21:47:54
User closed query 'Per source, 3.12. Please review and reconcile. ' (Site from CRA).		27 Dec 2020 21:47:52
Query 'Per source, 3.12. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Shannon Moyer (b) (4) (b) (4)	04 Dec 2020 06:48:24
User entered '3.12' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	04 Dec 2020 06:48:18
User opened query 'Per source, 3.12. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 17:50:05
DataPoint Un-verified.		03 Dec 2020 17:49:52
DataPoint Verified.		03 Dec 2020 17:49:47
User entered '3.21'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:12:41

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:17:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:49:49
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:12:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:17:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:50:07
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:12:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:17:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:50:09
User entered 'twice daily (BID)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:12:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:17:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:50:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:12:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:17:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:50:12
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:12:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:17:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:50:13
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:12:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:17:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:50:15
User entered '20 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:12:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:17:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:50:17
User entered '0'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:12:41

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:17:00
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:50:18
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:12:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:17:00

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:50:19
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:12:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:17:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:48:17
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:50:21
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 10:12:41

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	25 Nov 2020 10:12:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 10:12:41

US3252119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:17:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Nov 2020 10:12:41

US3252119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:17:00

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:40:39
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 16:08:22
User closed query 'Per ETRTR: Please add Procedure done for SAE "Myocardial Infarction", thanks' (Site from CRA).		09 Feb 2021 16:08:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:41:15
Query 'Per ETRTR: Please add Procedure done for SAE "Myocardial Infarction", thanks' answered with 'pending medical records from hospital' (Site from CRA).	Xavier Morales (b) (4) (b) (4)	27 Oct 2020 13:26:14
User opened query 'Per ETRTR: Please add Procedure done for SAE "Myocardial Infarction", thanks' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 21:00:30
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:05:39
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:47:49

US3252119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:17:00

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:57:37
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Nov 2020 09:44:38
User entered '14 Oct 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:44:38
DataPoint activated with code reason code Data required.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:43:44
DataPoint inactivated with code reason code Data not required.	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:06:10
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 14:48:35
User entered 'UN Nov 2016' (non-conformant).	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:48:35

US3252119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:17:00

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:57:39
User entered 'Emergent Left Heart Catherization' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:44:38
DataPoint activated with code reason code Data required.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:43:44
DataPoint inactivated with code reason code Data not required.	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:06:10
User entered 'Removal of 5th Left toe'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:48:35

US3252119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:57:41
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:47:08
DataPoint activated with code reason code Data required.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:43:44
DataPoint inactivated with code reason code Data not required.	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:06:10
User entered 'Other (OTHER)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:48:35

US3252119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:17:00

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:57:43
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:47:08
DataPoint activated with code reason code Data required.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:43:44
DataPoint inactivated with code reason code Data not required.	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:06:10
User entered 'Surgery'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:48:35

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:17:00

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:57:55
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Nov 2020 09:45:54
User entered '14 Oct 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:45:54
DataPoint activated with code reason code Data required.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:44:56
DataPoint inactivated with code reason code Data not required.	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:06:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 14:48:55
User entered 'UN Jan 2000' (non-conformant).	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:48:55

US3252119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:17:00

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:57:57
User entered 'percutaneous coronary intervention to the circumflex and left posterior descending artery' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:45:54
DataPoint activated with code reason code Data required.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:44:56
DataPoint inactivated with code reason code Data not required.	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:06:17
User entered 'Vasectomy'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:48:55

US3252119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:57:58
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:46:58
DataPoint activated with code reason code Data required.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:44:56
DataPoint inactivated with code reason code Data not required.	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:06:17
User entered 'Other (OTHER)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:48:55

US3252119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:17:00

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:57:59
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:46:58
DataPoint activated with code reason code Data required.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:44:56
DataPoint inactivated with code reason code Data not required.	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 02:06:17
User entered 'Surgery'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 14:48:55

US3252119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:17:00

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:58:10
User entered '15 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:46:41

US3252119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:17:00

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:58:08
User entered 'Percutaneous Coronary Intervention to left anterior descending artery'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:46:41

US3252119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:58:11
User entered 'Adverse Event (AE)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:46:41

US3252119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:17:00

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:58:13
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:46:41

US3252119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:17:00

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:47
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:58:18
User entered '14 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:48:07

US3252119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:17:00

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:47
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:58:21
User entered 'Attempted Percutaneous Coronary Intervention to the ramus unable to cross'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:48:07

US3252119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:17:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:47
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:58:22
User entered 'Adverse Event (AE)'	Shannon Moyer (b) (4) (b) (4)	25 Nov 2020 09:48:07

US3252119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:17:00

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:47
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:58:24
User entered empty.	Shannon Moyer (b) (4)	25 Nov 2020 09:48:07
	(b) (4)	

Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'USA-US108-2020-MRNA-1273-P301000006'	System	21 Oct 2020 20:35:40

US3252119
Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Yes (Y)'	System	21 Oct 2020 20:35:40

Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

US3252119

Folder: SAE USA-US108-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:00

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Yes (Y)'	System	21 Oct 2020 20:35:40

US3252119
Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Yes (Y)'	System	21 Oct 2020 20:35:40

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis　(b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Joel'	System	21 Oct 2020 20:35:40

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Solis'	System	21 Oct 2020 20:35:40

US3252119
Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:55:42
User closed query 'Please correct site street address to reflect correct street. ' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 17:55:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
Query 'Please correct site street address to reflect correct street. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 03:59:54
User entered '5201 N. 10TH STREET' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 03:59:48
Un-reviewed for Safety.		18 Feb 2021 05:32:23
DataPoint Un-verified.		18 Feb 2021 05:32:23
User entered '5201 N 10TH STREET' reason for change: Data Entry Error		18 Feb 2021 05:32:23
User opened query 'Please correct site street address to reflect correct street. ' (Site from CRA).		09 Feb 2021 14:49:50
DataPoint Verified.		03 Dec 2020 16:17:56
Reviewed for Safety.		21 Oct 2020 20:37:01
User entered '5201 N. 10th Street'	System	21 Oct 2020 20:35:40

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Mcallen'	System	21 Oct 2020 20:35:40

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'TX'	System	21 Oct 2020 20:35:40

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:55:46
User closed query 'Please correct site postal code to reflect correct postal code.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 17:55:44
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
Query 'Please correct site postal code to reflect correct postal code.' answered with 'the site postal code is correct' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 04:00:22
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 05:32:23
DataPoint Un-verified.		18 Feb 2021 05:32:23
User entered '78504' reason for change: Data Entry Error		18 Feb 2021 05:32:23
User opened query 'Please correct site postal code to reflect correct postal code.' (Site from CRA).		09 Feb 2021 14:50:07
DataPoint Verified.		03 Dec 2020 16:17:56
Reviewed for Safety.		21 Oct 2020 20:37:01
User entered 'carmpa'	System	21 Oct 2020 20:35:40

FDA-CBER-2022-1614-0715829

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:14:21
User entered 'US'	System	21 Oct 2020 20:37:08

FDA-CBER-2022-1614-0715830

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 18:52:43
User entered '3'	System	18 Nov 2020 13:21:08
User entered '2'	System	16 Nov 2020 22:14:33
User entered '1'	System	21 Oct 2020 20:37:08

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'USA-US108-2020-MRNA-1273-P301000006'	System	21 Oct 2020 20:35:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Yes (Y)'	System	21 Oct 2020 20:35:40

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Yes (Y)'	System	21 Oct 2020 20:35:40

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Yes (Y)'	System	21 Oct 2020 20:35:40

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Joel'	System	21 Oct 2020 20:35:40

Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Solis'	System	21 Oct 2020 20:35:40

US3252119
Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:55:42
User closed query 'Please correct site street address to reflect correct street. ' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 17:55:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
Query 'Please correct site street address to reflect correct street. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 03:59:54
User entered '5201 N. 10TH STREET' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 03:59:48
Un-reviewed for Safety.		18 Feb 2021 05:32:23
DataPoint Un-verified.		18 Feb 2021 05:32:23
User entered '5201 N 10TH STREET' reason for change: Data Entry Error		18 Feb 2021 05:32:23
User opened query 'Please correct site street address to reflect correct street. ' (Site from CRA).		09 Feb 2021 14:49:50
DataPoint Verified.		03 Dec 2020 16:17:56
Reviewed for Safety.		21 Oct 2020 20:37:01
User entered '5201 N. 10th Street'	System	21 Oct 2020 20:35:40

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Mcallen'	System	21 Oct 2020 20:35:40

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'TX'	System	21 Oct 2020 20:35:40

US3252119
Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:55:46
User closed query 'Please correct site postal code to reflect correct postal code.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 17:55:44
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
Query 'Please correct site postal code to reflect correct postal code.' answered with 'the site postal code is correct' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 04:00:22
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 05:32:23
DataPoint Un-verified.		18 Feb 2021 05:32:23
User entered '78504' reason for change: Data Entry Error		18 Feb 2021 05:32:23
User opened query 'Please correct site postal code to reflect correct postal code.' (Site from CRA).		09 Feb 2021 14:50:07
DataPoint Verified.		03 Dec 2020 16:17:56
Reviewed for Safety.		21 Oct 2020 20:37:01
User entered 'carmpa'	System	21 Oct 2020 20:35:40

US3252119

Folder: SAE USA-US108-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:00

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:14:21
User entered 'US'	System	21 Oct 2020 20:37:08

US3252119
Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 18:52:43
User entered '3'	System	18 Nov 2020 13:21:08
User entered '2'	System	16 Nov 2020 22:14:33
User entered '1'	System	21 Oct 2020 20:37:08

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
User entered '21/Oct/2020 20:37'	System	21 Oct 2020 20:37:08

FDA-CBER-2022-1614-0715848

US3252119

Folder: SAE USA-US108-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:17:00

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.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:14:21
User entered '1'	(b) (4), (b) (6)	21 Oct 2020 20:37:08

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'USA-US108-2020-MRNA-1273-P301000006'	System	21 Oct 2020 20:35:40

US3252119
Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Yes (Y)'	System	21 Oct 2020 20:35:40

US3252119
Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Yes (Y)'	System	21 Oct 2020 20:35:40

FDA-CBER-2022-1614-0715853

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Yes (Y)'	System	21 Oct 2020 20:35:40

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Joel'	System	21 Oct 2020 20:35:40

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Solis'	System	21 Oct 2020 20:35:40

US3252119
Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:55:42
User closed query 'Please correct site street address to reflect correct street. ' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 17:55:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
Query 'Please correct site street address to reflect correct street. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 03:59:54
User entered '5201 N. 10TH STREET' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 03:59:48
Un-reviewed for Safety.		18 Feb 2021 05:32:23
DataPoint Un-verified.		18 Feb 2021 05:32:23
User entered '5201 N 10TH STREET' reason for change: Data Entry Error		18 Feb 2021 05:32:23
User opened query 'Please correct site street address to reflect correct street. ' (Site from CRA).		09 Feb 2021 14:49:50
DataPoint Verified.		03 Dec 2020 16:17:56
Reviewed for Safety.		21 Oct 2020 20:37:01
User entered '5201 N. 10th Street'	System	21 Oct 2020 20:35:40

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Mcallen'	System	21 Oct 2020 20:35:40

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'TX'	System	21 Oct 2020 20:35:40

US3252119
Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:55:46
User closed query 'Please correct site postal code to reflect correct postal code.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 17:55:44
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
Query 'Please correct site postal code to reflect correct postal code.' answered with 'the site postal code is correct' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 04:00:22
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 05:32:23
DataPoint Un-verified.		18 Feb 2021 05:32:23
User entered '78504' reason for change: Data Entry Error		18 Feb 2021 05:32:23
User opened query 'Please correct site postal code to reflect correct postal code.' (Site from CRA).		09 Feb 2021 14:50:07
DataPoint Verified.		03 Dec 2020 16:17:56
Reviewed for Safety.		21 Oct 2020 20:37:01
User entered 'carmpa'	System	21 Oct 2020 20:35:40

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:14:21
User entered 'US'	System	21 Oct 2020 20:37:08

US3252119

Folder: SAE USA-US108-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:00

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 18:52:43
User entered '3'	System	18 Nov 2020 13:21:08
User entered '2'	System	16 Nov 2020 22:14:33
User entered '1'	System	21 Oct 2020 20:37:08

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
User entered '16/Nov/2020 22:14'	System	16 Nov 2020 22:14:33

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.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 13:20:55
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 22:14:33

Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'USA-US108-2020-MRNA-1273-P301000006'	System	21 Oct 2020 20:35:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Yes (Y)'	System	21 Oct 2020 20:35:40

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

US3252119
Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Yes (Y)'	System	21 Oct 2020 20:35:40

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Yes (Y)'	System	21 Oct 2020 20:35:40

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Joel'	System	21 Oct 2020 20:35:40

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Solis'	System	21 Oct 2020 20:35:40

US3252119
Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:55:42
User closed query 'Please correct site street address to reflect correct street. ' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 17:55:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
Query 'Please correct site street address to reflect correct street. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 03:59:54
User entered '5201 N. 10TH STREET' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 03:59:48
Un-reviewed for Safety.		18 Feb 2021 05:32:23
DataPoint Un-verified.		18 Feb 2021 05:32:23
User entered '5201 N 10TH STREET' reason for change: Data Entry Error		18 Feb 2021 05:32:23
User opened query 'Please correct site street address to reflect correct street. ' (Site from CRA).		09 Feb 2021 14:49:50
DataPoint Verified.		03 Dec 2020 16:17:56
Reviewed for Safety.		21 Oct 2020 20:37:01
User entered '5201 N. 10th Street'	System	21 Oct 2020 20:35:40

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Mcallen'	System	21 Oct 2020 20:35:40

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'TX'	System	21 Oct 2020 20:35:40

US3252119
Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:55:46
User closed query 'Please correct site postal code to reflect correct postal code.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 17:55:44
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
Query 'Please correct site postal code to reflect correct postal code.' answered with 'the site postal code is correct' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 04:00:22
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 05:32:23
DataPoint Un-verified.		18 Feb 2021 05:32:23
User entered '78504' reason for change: Data Entry Error		18 Feb 2021 05:32:23
User opened query 'Please correct site postal code to reflect correct postal code.' (Site from CRA).		09 Feb 2021 14:50:07
DataPoint Verified.		03 Dec 2020 16:17:56
Reviewed for Safety.		21 Oct 2020 20:37:01
User entered 'carmpa'	System	21 Oct 2020 20:35:40

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:14:21
User entered 'US'	System	21 Oct 2020 20:37:08

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 18:52:43
User entered '3'	System	18 Nov 2020 13:21:08
User entered '2'	System	16 Nov 2020 22:14:33
User entered '1'	System	21 Oct 2020 20:37:08

US3252119

Folder: SAE USA-US108-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:17:00

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ██ (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6) ██	03 Dec 2020 16:17:56
User entered '18/Nov/2020 13:21'	System	18 Nov 2020 13:21:08

US3252119

Folder: SAE USA-US108-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:17:00

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.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 18:52:34
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 13:21:08

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'USA-US108-2020-MRNA-1273-P301000006'	System	21 Oct 2020 20:35:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Yes (Y)'	System	21 Oct 2020 20:35:40

US3252119
Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▩(b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

US3252119
Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Yes (Y)'	System	21 Oct 2020 20:35:40

US3252119
Folder: SAE USA-US108-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 16:17:00
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Yes (Y)'	System	21 Oct 2020 20:35:40

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ████(b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6) ████	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6) ████	21 Oct 2020 20:37:01
User entered 'No (N)'	System	21 Oct 2020 20:35:40

FDA-CBER-2022-1614-0715893

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Joel'	System	21 Oct 2020 20:35:40

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Solis'	System	21 Oct 2020 20:35:40

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:55:42
User closed query 'Please correct site street address to reflect correct street. ' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 17:55:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
Query 'Please correct site street address to reflect correct street. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 03:59:54
User entered '5201 N. 10TH STREET' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 03:59:48
Un-reviewed for Safety.		18 Feb 2021 05:32:23
DataPoint Un-verified.		18 Feb 2021 05:32:23
User entered '5201 N 10TH STREET' reason for change: Data Entry Error		18 Feb 2021 05:32:23
User opened query 'Please correct site street address to reflect correct street. ' (Site from CRA).		09 Feb 2021 14:49:50
DataPoint Verified.		03 Dec 2020 16:17:56
Reviewed for Safety.		21 Oct 2020 20:37:01
User entered '5201 N. 10th Street'	System	21 Oct 2020 20:35:40

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'Mcallen'	System	21 Oct 2020 20:35:40

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered 'TX'	System	21 Oct 2020 20:35:40

US3252119

Folder: SAE USA-US108-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:00

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:55:46
User closed query 'Please correct site postal code to reflect correct postal code.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 17:55:44
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
Query 'Please correct site postal code to reflect correct postal code.' answered with 'the site postal code is correct' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 04:00:22
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 05:32:23
DataPoint Un-verified.		18 Feb 2021 05:32:23
User entered '78504' reason for change: Data Entry Error		18 Feb 2021 05:32:23
User opened query 'Please correct site postal code to reflect correct postal code.' (Site from CRA).		09 Feb 2021 14:50:07
DataPoint Verified.		03 Dec 2020 16:17:56
Reviewed for Safety.		21 Oct 2020 20:37:01
User entered 'carmpa'	System	21 Oct 2020 20:35:40

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:14:21
User entered 'US'	System	21 Oct 2020 20:37:08

US3252119

Folder: SAE USA-US108-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:00

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 18:52:43
User entered '3'	System	18 Nov 2020 13:21:08
User entered '2'	System	16 Nov 2020 22:14:33
User entered '1'	System	21 Oct 2020 20:37:08

US3252119

Folder: SAE USA-US108-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:17:00

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
User entered '24/Nov/2020 18:52'	System	24 Nov 2020 18:52:43

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.	Joel Solis (b) (4)	05 Mar 2021 20:13:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:17:56
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 18:52:43