US3042210 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:58:46

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US3042210
Form: Participant Creation
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

Participant ID	US3042210

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0191727

US3042210
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-0191728

US3042210
Folder: Screening
Form: Demographics
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	62
Age Units	YEARS
Age (Derived)	62
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

FDA-CBER-2022-1614-0191729

US3042210
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Date of Informed Consent *(dd MMM yyyy)*	17 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

FDA-CBER-2022-1614-0191730

US3042210
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Did the participant meet all eligibility criteria?	Yes ■ No ☐

FDA-CBER-2022-1614-0191731

US3042210
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-0191732

US3042210
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191733

US3042210
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0191734

US3042210
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0191735

US3042210
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Condition	ARCHNOID CYST ON LUMBAR SPINE
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0191736

US3042210
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	17 AUG 2020
Time of assessment *(00:00-23:59)*	09:20 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 09:20
Height *(xxx.x)*	193.0 cm
Weight *(xxx.x)*	97.1 kg
BMI *(xxx.x)*	26.06781 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)	

FDA-CBER-2022-1614-0191737

US3042210
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

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.

FDA-CBER-2022-1614-0191738

US3042210
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **28 Apr 2021 15:16:36**
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Occupational Risk	
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☐ No ☐
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐ No ☐
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐ No ☐
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐ No ☐
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐ No ☐
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐ No ☐
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐ No ☐
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐ No ☐
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐ No ☐
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐ No ☐
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐ No ☐
Other	Yes ☐ No ☐
Specify	

Location and Living Circumstances Risk (check all that apply)	
No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False

FDA-CBER-2022-1614-0191739

US3042210
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

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	

FDA-CBER-2022-1614-0191740

US3042210
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-0191741

US3042210
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

What was the date of randomization? *(dd MMM yyyy)*	17 AUG 2020
What was the participant's randomization number?	104611
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 ■

FDA-CBER-2022-1614-0191742

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-0191743

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

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)*	17 AUG 2020
Time of assessment *(00:00-23:59)*	09:20 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 09:20
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	62 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0191744

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

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)*	17 AUG 2020
Time of assessment *(00:00-23:59)*	10:55 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 10:55
Temperature *(xxx.x)*	36.5 C
Route of measurement	Oral ● Axillary ○ Other ○
If Other, specify	
Pulse *(xxx)*	53 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	88 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0191745

US3042210
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	17 AUG 2020

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

FDA-CBER-2022-1614-0191746

US3042210
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

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)*	17 AUG 2020
What was the treatment time? *(00:00-23:59)*	10:18 (24 HR)
Treatment Date and Time (derived)	17 AUG 2020 10:18
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-0191747

US3042210
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	17 AUG 2020
Collection time *(00:00-23:59)*	09:47 (24 HR)
Collection date and time (derived)	17 AUG 2020 09:47

FDA-CBER-2022-1614-0191748

US3042210
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Collection date *(dd MMM yyyy)*			17 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:35	17 AUG 2020 09:35
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0191749

US3042210
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0191750

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**	97.7 °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	17 AUG 2020 10:52
PC Open Date & Time	17 AUG 2020 10:38
PC Close Date & Time	17 AUG 2020 13:08

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	17 AUG 2020 19:25
PC Open Date & Time	17 AUG 2020 14:03
PC Close Date & Time	18 AUG 2020 11:59

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:58:46

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**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 AUG 2020 19:40
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:58:46

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.6 °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	19 AUG 2020 19:33
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

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	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:58:46

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	21 AUG 2020 20:41
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:58:46

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	22 AUG 2020 19:36
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:58:46

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °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	23 AUG 2020 20:40
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:58:46

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	17 AUG 2020 10:53
PC Open Date & Time	17 AUG 2020 10:38
PC Close Date & Time	17 AUG 2020 13:08

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:58:46

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	17 AUG 2020 19:26
PC Open Date & Time	17 AUG 2020 14:03
PC Close Date & Time	18 AUG 2020 11:59

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:58:46

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	18 AUG 2020 19:41
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

FDA-CBER-2022-1614-0191761

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:58:46

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	19 AUG 2020 19:33
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

FDA-CBER-2022-1614-0191762

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46

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	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:58:46

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	21 AUG 2020 20:41
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

FDA-CBER-2022-1614-0191764

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:58:46

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	22 AUG 2020 19:36
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

FDA-CBER-2022-1614-0191765

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:58:46

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	23 AUG 2020 20:41
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

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 ☐

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	17 AUG 2020 10:54
PC Open Date & Time	17 AUG 2020 10:38
PC Close Date & Time	17 AUG 2020 13:08

FDA-CBER-2022-1614-0191768

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46

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 ☐

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	17 AUG 2020 19:26
PC Open Date & Time	17 AUG 2020 14:03
PC Close Date & Time	18 AUG 2020 11:59

FDA-CBER-2022-1614-0191770

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 ■

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46

	Yes ☐
PC Time stamp	18 AUG 2020 19:41
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

FDA-CBER-2022-1614-0191772

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 ■

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46

	Yes ☐
PC Time stamp	19 AUG 2020 19:34
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

FDA-CBER-2022-1614-0191774

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	
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 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 ■

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46

	Yes ☐
PC Time stamp	21 AUG 2020 20:41
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

FDA-CBER-2022-1614-0191778

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 ■

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46

	Yes ☐
PC Time stamp	22 AUG 2020 19:37
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

TIMEPOINT	DAY 7
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46

	Yes
PC Time stamp	23 AUG 2020 20:41
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3042210
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	24 AUG 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0191783

US3042210
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0191784

US3042210
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

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*	

FDA-CBER-2022-1614-0191785

US3042210
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0191786

US3042210
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	08 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

US3042210
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0191788

US3042210
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-0191789

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	14 SEP 2020
Time of assessment *(00:00-23:59)*	17:14 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 17:14
Temperature *(xxx.x)*	36.5 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	61 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	88 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0191790

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	14 SEP 2020
Time of assessment *(00:00-23:59)*	18:08 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 18:08
Temperature *(xxx.x)*	36.8 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	64 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	84 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0191791

US3042210
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	14 SEP 2020

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

FDA-CBER-2022-1614-0191792

US3042210
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

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)*	14 SEP 2020
What was the treatment time? *(00:00-23:59)*	17:36 (24 HR)
Treatment Date and Time (derived)	14 SEP 2020 17:36
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-0191793

US3042210
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	14 SEP 2020
Collection time *(00:00-23:59)*	17:22 (24 HR)
Collection date and time (derived)	14 SEP 2020 17:22

FDA-CBER-2022-1614-0191794

US3042210
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Collection date *(dd MMM yyyy)*			14 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:17	14 SEP 2020 17:17
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0191795

US3042210
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0191796

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:58:46

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	14 SEP 2020 18:11
PC Open Date & Time	14 SEP 2020 17:56
PC Close Date & Time	14 SEP 2020 20:26

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	14 SEP 2020 21:39
PC Open Date & Time	14 SEP 2020 21:21
PC Close Date & Time	15 SEP 2020 11:59

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:58:46

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**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	15 SEP 2020 19:50
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:58:46

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	16 SEP 2020 21:02
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:58:46

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**	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	17 SEP 2020 21:11
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:58:46

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	18 SEP 2020 19:19
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:58:46

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	97.3 °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	20 SEP 2020 02:30
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:58:46

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**	97.7 °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	20 SEP 2020 22:47
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:58:46

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	14 SEP 2020 18:12
PC Open Date & Time	14 SEP 2020 17:56
PC Close Date & Time	14 SEP 2020 20:26

FDA-CBER-2022-1614-0191805

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:58:46

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	14 SEP 2020 21:39
PC Open Date & Time	14 SEP 2020 21:21
PC Close Date & Time	15 SEP 2020 11:59

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:58:46

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	15 SEP 2020 19:51
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:58:46

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	16 SEP 2020 21:02
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

FDA-CBER-2022-1614-0191808

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46

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	17 SEP 2020 21:12
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

FDA-CBER-2022-1614-0191809

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:58:46

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	18 SEP 2020 19:19
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:58:46

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	20 SEP 2020 02:31
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:58:46

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	20 SEP 2020 22:48
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

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 ☐

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	14 SEP 2020 18:12
PC Open Date & Time	14 SEP 2020 17:56
PC Close Date & Time	14 SEP 2020 20:26

FDA-CBER-2022-1614-0191814

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 ☐

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	14 SEP 2020 21:39
PC Open Date & Time	14 SEP 2020 21:21
PC Close Date & Time	15 SEP 2020 11:59

FDA-CBER-2022-1614-0191816

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 ■

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46

	Yes ☐
PC Time stamp	15 SEP 2020 19:51
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

FDA-CBER-2022-1614-0191818

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 ■

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46

	Yes ☐
PC Time stamp	16 SEP 2020 21:02
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

FDA-CBER-2022-1614-0191820

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46

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-2022-1614-0191821

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46

	Yes ☐
PC Time stamp	17 SEP 2020 21:12
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

FDA-CBER-2022-1614-0191822

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46

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 ■

FDA-CBER-2022-1614-0191823

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46

	Yes
PC Time stamp	18 SEP 2020 19:21
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-0191824

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46

TIMEPOINT	DAY 6
HEADACHE	None ☐
	No interference with activity ■
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ☐
	No interference with activity ■
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-0191825

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46

	Yes
PC Time stamp	20 SEP 2020 02:31
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

FDA-CBER-2022-1614-0191826

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46

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 ■

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46

	Yes
PC Time stamp	20 SEP 2020 22:48
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

FDA-CBER-2022-1614-0191828

US3042210
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	25 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3042210
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0191830

US3042210
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	28 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0191831

US3042210
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0191832

US3042210
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	05 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3042210
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0191834

US3042210
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-0191835

US3042210
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	12 OCT 2020
Time of assessment *(00:00-23:59)*	13:01 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 13:01
Temperature *(xxx.x)*	36.4 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0191836

US3042210
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	12 OCT 2020

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

FDA-CBER-2022-1614-0191837

US3042210
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	12 OCT 2020
Collection time *(00:00-23:59)*	13:10 (24 HR)
Collection date and time (derived)	12 OCT 2020 13:10

US3042210
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0191839

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 OCT 2020 14:36:20
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

FDA-CBER-2022-1614-0191840

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 OCT 2020 21:35:10
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

FDA-CBER-2022-1614-0191841

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 NOV 2020 22:13:12
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

FDA-CBER-2022-1614-0191842

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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	17 NOV 2020 20:17:48
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

FDA-CBER-2022-1614-0191843

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 16:51:13
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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	29 NOV 2020 12:46:10
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

FDA-CBER-2022-1614-0191845

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

FDA-CBER-2022-1614-0191847

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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	17 DEC 2020 20:52:52
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

FDA-CBER-2022-1614-0191850

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

FDA-CBER-2022-1614-0191854

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 19:31:37
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

FDA-CBER-2022-1614-0191857

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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191859

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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	28 JAN 2021 16:23:59
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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	03 FEB 2021 20:03:10
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

FDA-CBER-2022-1614-0191861

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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	12 FEB 2021 13:24:38
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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	18 FEB 2021 14:43:29
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

FDA-CBER-2022-1614-0191863

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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	24 FEB 2021 16:38:59
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

FDA-CBER-2022-1614-0191866

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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	11 MAR 2021 22:07:09
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

FDA-CBER-2022-1614-0191867

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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	21 MAR 2021 21:33:41
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

FDA-CBER-2022-1614-0191868

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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	03 APR 2021 22:47:20
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 APR 2021 08:32:59
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

FDA-CBER-2022-1614-0191872

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191874

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

FDA-CBER-2022-1614-0191876

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	02 MAY 2021 23:59

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	09 MAY 2021 23:59

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	16 MAY 2021 23:59

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191886

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	06 JUN 2021 23:59

FDA-CBER-2022-1614-0191888

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	13 JUN 2021 23:59

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	20 JUN 2021 23:59

FDA-CBER-2022-1614-0191892

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191894

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191896

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
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Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	11 JUL 2021 23:59

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191900

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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

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 ≥ 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 ☐

US3042210
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	01 AUG 2021 23:59

FDA-CBER-2022-1614-0191904

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
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Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	08 AUG 2021 23:59

FDA-CBER-2022-1614-0191906

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3042210
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Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	15 AUG 2021 23:59

FDA-CBER-2022-1614-0191908

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	22 AUG 2021 23:59

FDA-CBER-2022-1614-0191910

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 ≥ 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 ☐

US3042210
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	29 AUG 2021 23:59

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 ≥ 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 ☐

US3042210
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	05 SEP 2021 23:59

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191916

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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	26 SEP 2021 23:59

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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191922

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	10 OCT 2021 23:59

FDA-CBER-2022-1614-0191924

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191926

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191928

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191930

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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191932

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
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Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191934

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
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Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 NOV 2021 00:01
Patient Cloud Close Date & Time	21 NOV 2021 23:59

FDA-CBER-2022-1614-0191936

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 NOV 2021 00:01
Patient Cloud Close Date & Time	28 NOV 2021 23:59

FDA-CBER-2022-1614-0191938

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

FDA-CBER-2022-1614-0191940

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191942

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191944

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

FDA-CBER-2022-1614-0191946

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

FDA-CBER-2022-1614-0191948

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 JAN 2022 00:01
Patient Cloud Close Date & Time	09 JAN 2022 23:59

FDA-CBER-2022-1614-0191950

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 JAN 2022 00:01
Patient Cloud Close Date & Time	16 JAN 2022 23:59

FDA-CBER-2022-1614-0191952

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191954

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 JAN 2022 00:01
Patient Cloud Close Date & Time	30 JAN 2022 23:59

FDA-CBER-2022-1614-0191956

TIMEPOINT	DAY 537
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3042210
Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 FEB 2022 00:01
Patient Cloud Close Date & Time	06 FEB 2022 23:59

FDA-CBER-2022-1614-0191958

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 FEB 2022 00:01
Patient Cloud Close Date & Time	13 FEB 2022 23:59

FDA-CBER-2022-1614-0191960

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 FEB 2022 00:01
Patient Cloud Close Date & Time	20 FEB 2022 23:59

TIMEPOINT	DAY 558
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
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Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 FEB 2022 00:01
Patient Cloud Close Date & Time	27 FEB 2022 23:59

FDA-CBER-2022-1614-0191964

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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAR 2022 00:01
Patient Cloud Close Date & Time	06 MAR 2022 23:59

FDA-CBER-2022-1614-0191966

TIMEPOINT	DAY 572
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAR 2022 00:01
Patient Cloud Close Date & Time	13 MAR 2022 23:59

FDA-CBER-2022-1614-0191968

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 ≥ 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 ☐

US3042210
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAR 2022 00:01
Patient Cloud Close Date & Time	20 MAR 2022 23:59

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAR 2022 00:01
Patient Cloud Close Date & Time	27 MAR 2022 23:59

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAR 2022 00:01
Patient Cloud Close Date & Time	03 APR 2022 23:59

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 APR 2022 00:01
Patient Cloud Close Date & Time	10 APR 2022 23:59

FDA-CBER-2022-1614-0191976

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191978

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191980

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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAY 2022 00:01
Patient Cloud Close Date & Time	08 MAY 2022 23:59

FDA-CBER-2022-1614-0191984

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAY 2022 00:01
Patient Cloud Close Date & Time	15 MAY 2022 23:59

FDA-CBER-2022-1614-0191986

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAY 2022 00:01
Patient Cloud Close Date & Time	22 MAY 2022 23:59

FDA-CBER-2022-1614-0191988

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAY 2022 00:01
Patient Cloud Close Date & Time	29 MAY 2022 23:59

FDA-CBER-2022-1614-0191990

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 JUN 2022 00:01
Patient Cloud Close Date & Time	05 JUN 2022 23:59

FDA-CBER-2022-1614-0191992

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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
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Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0191994

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
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Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 JUN 2022 00:01
Patient Cloud Close Date & Time	19 JUN 2022 23:59

FDA-CBER-2022-1614-0191996

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 JUN 2022 00:01
Patient Cloud Close Date & Time	26 JUN 2022 23:59

FDA-CBER-2022-1614-0191998

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 ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 JUN 2022 00:01
Patient Cloud Close Date & Time	03 JUL 2022 23:59

FDA-CBER-2022-1614-0192000

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 JUL 2022 00:01
Patient Cloud Close Date & Time	10 JUL 2022 23:59

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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0192004

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0192006

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 AUG 2022 00:01
Patient Cloud Close Date & Time	07 AUG 2022 23:59

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 AUG 2022 00:01
Patient Cloud Close Date & Time	21 AUG 2022 23:59

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0192016

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 AUG 2022 00:01
Patient Cloud Close Date & Time	04 SEP 2022 23:59

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
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Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 SEP 2022 00:01
Patient Cloud Close Date & Time	11 SEP 2022 23:59

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3042210
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Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 SEP 2022 00:01
Patient Cloud Close Date & Time	18 SEP 2022 23:59

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 SEP 2022 00:01
Patient Cloud Close Date & Time	25 SEP 2022 23:59

FDA-CBER-2022-1614-0192024

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 ≥ 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 ☐

US3042210
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 SEP 2022 00:01
Patient Cloud Close Date & Time	02 OCT 2022 23:59

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 ☐

US3042210
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	05 OCT 2022 00:01
Patient Cloud Close Date & Time	09 OCT 2022 23:59

FDA-CBER-2022-1614-0192028

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 ≥ 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 ☐

US3042210
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46

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

US3042210
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 09 Jun 2021 14:58:46

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		12 MAR 2021 09:47:31

FDA-CBER-2022-1614-0192033

US3042210
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	11 NOV 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3042210
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0192035

US3042210
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	10 DEC 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3042210
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0192037

US3042210
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	11 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3042210
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0192039

US3042210
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	09 FEB 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0192040

US3042210
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0192041

US3042210
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	01 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT4

FDA-CBER-2022-1614-0192042

US3042210
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

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)	

FDA-CBER-2022-1614-0192043

US3042210
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

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.

FDA-CBER-2022-1614-0192044

US3042210
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	01 MAR 2021
Collection time *(00:00-23:59)*	08:23 (24 HR)
Collection date and time (derived)	01 MAR 2021 08:23

US3042210
Folder: Visit 4 Day 209 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:37**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0192046

US3042210
Folder: Safety Call Day 239 (1)
Form: Safety Call
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	13 APR 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3042210
Folder: Safety Call Day 239 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0192048

US3042210
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46

Was Contact Attempted?	Yes ☐ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	
Please select one status for the follow-up contact	Contact Made ☐ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

Is the participant continuing to the next visit?	Yes ☐ No ☐
Continuing Flag	

US3042210
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 14:58:46

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 ☐

FDA-CBER-2022-1614-0192051

Generate Next COVID-19 Assessment	Yes ☐ No ☐

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **28 Apr 2021 15:16:35**
Generated On: 09 Jun 2021 14:58:46

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	11 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	UNBLND_DECIDE

FDA-CBER-2022-1614-0192053

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **28 Apr 2021 15:16:35**
Generated On: 09 Jun 2021 14:58:46

Date of updated informed consent *(dd MMM yyyy)*	11 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)*	11 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

FDA-CBER-2022-1614-0192054

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Data signed: (b) (4) **28 Apr 2021 15:16:35**
Generated On: 09 Jun 2021 14:58:46

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

FDA-CBER-2022-1614-0192055

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **28 Apr 2021 15:16:35**
Generated On: 09 Jun 2021 14:58:46

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)*	11 JAN 2021
Time of assessment *(00:00-23:59)*	09:00 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 09:00
Temperature *(xxx.x)*	36.8 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	62 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 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

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **28 Apr 2021 15:16:35**
Generated On: 09 Jun 2021 14:58:46

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)*	11 JAN 2021
Time of assessment *(00:00-23:59)*	10:08 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 10:08
Temperature *(xxx.x)*	37.1 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	69 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0192057

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Data signed: (b) (4) **28 Apr 2021 15:16:35**
Generated On: 09 Jun 2021 14:58:46

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	11 JAN 2021

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

FDA-CBER-2022-1614-0192058

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Data signed: (b) (4) **28 Apr 2021 15:16:25**
Generated On: 09 Jun 2021 14:58:46

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	11 JAN 2021
What was the treatment time? *(00:00-23:59)*	09:34 (24 HR)
Treatment Date and Time (derived)	11 JAN 2021 09:34
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-0192059

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **28 Apr 2021 15:16:35**
Generated On: 09 Jun 2021 14:58:46

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	11 JAN 2021
Collection time *(00:00-23:59)*	08:42 (24 HR)
Collection date and time (derived)	11 JAN 2021 08:42

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **28 Apr 2021 15:16:25**
Generated On: 09 Jun 2021 14:58:46

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	11 JAN 2021
Collection time *(00:00 - 23:59)*	09:00
Collection Date and Time (derived)	11 JAN 2021 09:00

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:25**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0192062

US3042210
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	19 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3042210
Folder: Safety Call OL-D8 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1
OLD29 Placebo Flag	1

FDA-CBER-2022-1614-0192064

US3042210
Folder: OL-D29 (1)
Form: Visit Date
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	08 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	OLD29

FDA-CBER-2022-1614-0192065

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	08 FEB 2021
Time of assessment *(00:00-23:59)*	08:20 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 08:20
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	86 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0192066

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	08 FEB 2021
Time of assessment *(00:00-23:59)*	09:35 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 09:35
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	76 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

US3042210
Folder: OL-D29 (1)
Form: Physical Examination
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	08 FEB 2021

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

US3042210
Folder: OL-D29 (1)
Form: Exposure
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

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)*	08 FEB 2021
What was the treatment time? *(00:00-23:59)*	09:04 (24 HR)
Treatment Date and Time (derived)	08 FEB 2021 09:04
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-0192069

US3042210
Folder: OL-D29 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0192070

US3042210
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 FEB 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3042210
Folder: Safety Call OL-D36 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0192072

US3042210
Folder: OL-D57 (1)
Form: Visit Date
Data signed: (b) (4) **28 Apr 2021 15:16:25**
Generated On: 09 Jun 2021 14:58:46

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	15 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	OLD57

FDA-CBER-2022-1614-0192073

US3042210
Folder: OL-D57 (1)
Form: Vital Signs
Data signed: (b) (4) **28 Apr 2021 15:16:25**
Generated On: 09 Jun 2021 14:58:46

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	15 MAR 2021
Time of assessment *(00:00-23:59)*	08:05 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 08:05
Temperature *(xxx.x)*	37.0 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042210
Folder: OL-D57 (1)
Form: Physical Examination
Data signed: (b) (4) **28 Apr 2021 15:16:25**
Generated On: 09 Jun 2021 14:58:46

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.

US3042210
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **28 Apr 2021 15:16:25**
Generated On: 09 Jun 2021 14:58:46

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	15 MAR 2021
Collection time *(00:00-23:59)*	08:15 (24 HR)
Collection date and time (derived)	15 MAR 2021 08:15

US3042210
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

Did the participant experience any adverse events?	Yes ■ No ☐

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-0192077

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

AEID	USA-US052-2020-MRNA-1273-P301000020
Adverse event	GROWING/WORSENING OF ARACHNOID CYST ON LUMBAR SPINE
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)*	01 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	03 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	03 NOV 2020
Hospital Discharge Date *(dd MMM yyyy)*	06 NOV 2020
Admitted to ICU?	Yes ☐ No ■

	Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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 HAD SURGICAL EXCISION OF ARACHNOID CYST ON LUMBAR SPINE AND WAS IN PATIENT AT SURGICAL CENTER FROM 03NOV-06NOV
Serious Adverse Event Derived (CSA Programming Field Ony)	1

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

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

US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

AEID	
Adverse event	BILATERAL LOWER LEG NEURALGIA
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)*	03 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ■ No ☐
If not Ongoing, end date *(dd MMM yyyy)*	
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ■ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ■ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

Were any prior/concomitant medications and/or vaccinations taken?	Yes ■ No ☐

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

FDA-CBER-2022-1614-0192083

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

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

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

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2017
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 ■

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2017
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 ■

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

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

	Intramuscular ☐
	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 2015
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 ■

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ■
Indication	SOLICITED SYMPTOM-HEADACHE
Dose per administration	1000
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	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)*	17 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	20 SEP 2020
Was this medication taken for solicited event?	Yes ■ No ☐
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

Name of Medication	GABAPENTIN
Prophylaxis	Yes ☐ No ■
Indication	BILATERAL LOWER LEG NEURALGIA
Dose per administration	800
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ■ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	03 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

Name of Medication	CYMBALTA
Prophylaxis	Yes ☐ No ■
Indication	BILATERAL LOWER LEG NEURALGIA
Dose per administration	60
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	03 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3042210
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

Were any concomitant procedures performed?	Yes ■ No ☐

If yes, please complete Concomitant Procedures form.

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US3042210
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures
Data signed: (b) (4) **28 Apr 2021 15:16:24**
Generated On: 09 Jun 2021 14:58:46

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
03 NOV 2020	SURGICAL EXCISION OF ARACHNOID CYST OVER LUMBER SPINE	Adverse Event	

FDA-CBER-2022-1614-0192099

US3042210
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 14:58:46

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	_____

FDA-CBER-2022-1614-0192100

US3042210
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:58:46

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 ☐

FDA-CBER-2022-1614-0192101

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

SAEID	USA-US052-2020-MRNA-1273-P301000020
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form (1)
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

SAEID	USA-US052-2020-MRNA-1273-P301000020
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	01/DEC/2020 11:14
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

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form (2)
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

SAEID	USA-US052-2020-MRNA-1273-P301000020
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	09/DEC/2020 18:19
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

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form (3)
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

SAEID	USA-US052-2020-MRNA-1273-P301000020
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	14/DEC/2020 12:02
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

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form (4)
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

SAEID	USA-US052-2020-MRNA-1273-P301000020
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/JAN/2021 13:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form (5)
Data signed: (b) (4) **28 Apr 2021 15:16:36**
Generated On: 09 Jun 2021 14:58:46

SAEID	USA-US052-2020-MRNA-1273-P301000020
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	08/APR/2021 12:37
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

Audit

US3042210 (Prod: Meridian Clinical Research)

US3042210
Form: Participant Creation
Generated On: 09 Jun 2021 14:58:46
Participant ID

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:30:31
User entered 'US3042210'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 14:54:40

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US3042210
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:12:39
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:24:39

US3042210
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:12:39
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 14:54:45

FDA-CBER-2022-1614-0192111

US3042210
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:12:39
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:24:39

FDA-CBER-2022-1614-0192112

US3042210
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered 'SCRN'	System	17 Aug 2020 19:24:39

FDA-CBER-2022-1614-0192113

US3042210
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:58:46
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:13:31
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1, and Visit2 Day29: Year of Birth (1958) recorded on this form does not match with the Year of birth (1950) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:17:48
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1, and Visit2 Day29: Year of Birth (1958) recorded on this form does not match with the Year of birth (1950) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' answered with 'YEAR OF BIRTH IS CORRECT. ' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 13:31:59
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1, and Visit2 Day29: Year of Birth (1958) recorded on this form does not match with the Year of birth (1950) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 07:32:35
User entered (b) (6) 1958'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 14:54:49

FDA-CBER-2022-1614-0192114

US3042210
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:58:46
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:13:31
User entered '62'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:24:44

FDA-CBER-2022-1614-0192115

US3042210
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:58:46
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered 'YEARS'	System	17 Aug 2020 19:24:44

FDA-CBER-2022-1614-0192116

US3042210
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:58:46
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered '62'	System	17 Aug 2020 15:20:30

FDA-CBER-2022-1614-0192117

US3042210
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:58:46
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:13:31
User closed query 'Per GCL Lab Recon: Re-query: Response noted, however Please confirm sex of the subject(Male) in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 19:16:05
Query 'Per GCL Lab Recon: Re-query: Response noted, however Please confirm sex of the subject(Male) in EDC. Thank you.' answered with 'Sex of the subject is correct.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 14:13:34
User opened query 'Per GCL Lab Recon: Re-query: Response noted, however Please confirm sex of the subject(Male) in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:09:52
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit2 Day29 : Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:17:53
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit2 Day29 : Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' answered with 'SEX IS CORRECT' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 13:32:34
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit2 Day29 : Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 07:34:09
User entered 'Male (M)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:24:44

FDA-CBER-2022-1614-0192118

US3042210
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:58:46
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:13:31
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:24:44

FDA-CBER-2022-1614-0192119

US3042210
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:58:46
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:13:31
User entered '1'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:24:44

FDA-CBER-2022-1614-0192120

US3042210
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:58:46
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:13:31
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:24:44

FDA-CBER-2022-1614-0192121

US3042210
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:58:46
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:13:31
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:24:44

FDA-CBER-2022-1614-0192122

US3042210
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:58:46
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:13:31
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:24:44

FDA-CBER-2022-1614-0192123

US3042210
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:58:46
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:13:31
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:24:44

FDA-CBER-2022-1614-0192124

US3042210
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:58:46
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:13:31
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:24:44

FDA-CBER-2022-1614-0192125

US3042210
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:58:46
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:13:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:24:44

US3042210
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:58:46
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:13:31
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:24:44

FDA-CBER-2022-1614-0192127

US3042210
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:58:46
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:13:31
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:24:44

FDA-CBER-2022-1614-0192128

US3042210
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:58:46
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:14:03
User entered '17 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 15:20:30

FDA-CBER-2022-1614-0192129

US3042210
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:58:46
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered 'Aug 2020'	System	17 Aug 2020 15:20:30

FDA-CBER-2022-1614-0192130

US3042210
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:58:46
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered '2020'	System	17 Aug 2020 15:20:30

FDA-CBER-2022-1614-0192131

US3042210
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:58:46
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:14:03
User entered 'Amendment 2 (2)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 15:20:30

US3042210
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:58:46
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:14:03
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 15:20:30

US3042210
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:58:46
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:14:03
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 15:20:30

FDA-CBER-2022-1614-0192134

US3042210
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:58:46
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:14:03
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 15:20:30

US3042210
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:58:46
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:14:03
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 15:20:30

FDA-CBER-2022-1614-0192136

US3042210
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:58:46
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:14:03
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 14:54:45

FDA-CBER-2022-1614-0192137

US3042210
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:58:46
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered '1'	System	17 Aug 2020 15:20:32

FDA-CBER-2022-1614-0192138

US3042210
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 14:58:46
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:14:14
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 15:20:32

US3042210
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 14:58:46
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:14:21
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:01

US3042210
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:58:46
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
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)	17 Aug 2020 19:27:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 19:27:13
Data point term sent to Coder	System	17 Aug 2020 19:26:02
User entered 'HYPERTENSION'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:11

FDA-CBER-2022-1614-0192141

US3042210
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:58:46
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered 'UN UNK 2010'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:11

FDA-CBER-2022-1614-0192142

US3042210
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:58:46
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:11

FDA-CBER-2022-1614-0192143

US3042210
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:58:46
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:11

US3042210
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:58:46
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:11

US3042210
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:58:46
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:11

FDA-CBER-2022-1614-0192146

US3042210
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:58:46
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered 'Jan 2010'	System	17 Aug 2020 19:25:11

US3042210
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:58:46
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered '2010'	System	17 Aug 2020 19:25:11

FDA-CBER-2022-1614-0192148

US3042210
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:58:46
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered empty.	System	17 Aug 2020 19:25:11

US3042210
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:58:46
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered empty.	System	17 Aug 2020 19:25:11

FDA-CBER-2022-1614-0192150

US3042210
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:58:46
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
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)	17 Aug 2020 19:27:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 19:27:13
Data point term sent to Coder	System	17 Aug 2020 19:26:02
User entered 'HYPERLIPIDEMIA'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:43

FDA-CBER-2022-1614-0192151

US3042210
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:58:46
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered 'UN UNK 2017'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:43

FDA-CBER-2022-1614-0192152

US3042210
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:58:46
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:43

FDA-CBER-2022-1614-0192153

US3042210
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:58:46
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:43

FDA-CBER-2022-1614-0192154

US3042210
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:58:46
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:43

US3042210
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:58:46
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:43

FDA-CBER-2022-1614-0192156

US3042210
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:58:46
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered 'Jan 2017'	System	17 Aug 2020 19:25:43

US3042210
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:58:46
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered '2017'	System	17 Aug 2020 19:25:43

FDA-CBER-2022-1614-0192158

US3042210
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:58:46
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered empty.	System	17 Aug 2020 19:25:43

FDA-CBER-2022-1614-0192159

US3042210
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:58:46
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered empty.	System	17 Aug 2020 19:25:43

FDA-CBER-2022-1614-0192160

US3042210
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:58:46
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 19:27:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 19:27:14
Data point term sent to Coder	System	17 Aug 2020 19:26:02
User entered 'HYPOTHYROIDISM'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:52

US3042210
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:58:46
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered 'UN UNK 2015'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:52

FDA-CBER-2022-1614-0192162

US3042210
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:58:46
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:52

FDA-CBER-2022-1614-0192163

US3042210
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:58:46
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:52

FDA-CBER-2022-1614-0192164

US3042210
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:58:46
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:52

FDA-CBER-2022-1614-0192165

US3042210
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:58:46
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:25:52

US3042210
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:58:46
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered 'Jan 2015'	System	17 Aug 2020 19:25:52

FDA-CBER-2022-1614-0192167

US3042210
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:58:46
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered '2015'	System	17 Aug 2020 19:25:52

FDA-CBER-2022-1614-0192168

US3042210
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:58:46
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered empty.	System	17 Aug 2020 19:25:52

FDA-CBER-2022-1614-0192169

US3042210
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:58:46
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered empty.	System	17 Aug 2020 19:25:52

US3042210
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:58:46
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User coded data point as SOC: Nervous system disorders, HLGT: Nervous system neoplasms benign, HLT: Nervous system cysts and polyps, PT: Arachnoid cyst, LLT: Arachnoid cyst - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 16:48:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 16:48:49
Data point term sent to Coder	System	11 Dec 2020 16:10:51
User entered 'ARCHNOID CYST ON LUMBAR SPINE'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:10:44

FDA-CBER-2022-1614-0192171

US3042210
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:58:46
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered 'UN UNK 2015'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:10:44

US3042210
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:58:46
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:10:44

FDA-CBER-2022-1614-0192173

US3042210
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:58:46
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:10:44

US3042210
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:58:46
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:10:44

FDA-CBER-2022-1614-0192175

US3042210
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:58:46
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:46:57
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:10:44

US3042210
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:58:46
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered 'Jan 2015'	System	11 Dec 2020 16:10:44

FDA-CBER-2022-1614-0192177

US3042210
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:58:46
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered '2015'	System	11 Dec 2020 16:10:44

FDA-CBER-2022-1614-0192178

US3042210
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:58:46
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered empty.	System	11 Dec 2020 16:10:44

FDA-CBER-2022-1614-0192179

US3042210
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:58:46
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered empty.	System	11 Dec 2020 16:10:44

FDA-CBER-2022-1614-0192180

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:47:55
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:22

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:47:55
User entered '17 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:22

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:47:55
User entered '09:20'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:22

FDA-CBER-2022-1614-0192183

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered '17 Aug 2020 09:20'	(b) (4), (b) (6) System	17 Aug 2020 19:26:22

FDA-CBER-2022-1614-0192184

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:47:55
User entered '193.0' cm	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:22
DataPoint set to visible.	System	17 Aug 2020 15:20:32

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:47:55
User entered '97.1' kg	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:22
DataPoint set to visible.	System	17 Aug 2020 15:20:32

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:03
	(b) (4), (b) (6)	
Amendment Manager: User entered '26.06781'	System	16 Sep 2020 23:59:40
User entered '26.1'	System	17 Aug 2020 19:26:22
DataPoint set to visible.	System	17 Aug 2020 15:20:32

FDA-CBER-2022-1614-0192187

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered 'kg/m2'	System	17 Aug 2020 19:26:22
DataPoint set to visible.	System	17 Aug 2020 15:20:32

FDA-CBER-2022-1614-0192188

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:47:55
User closed query 'Per CDM : Kindly remove the unit for temperature, Thanks' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 07:00:07
Query 'Per CDM : Kindly remove the unit for temperature, Thanks' answered with 'entry updated' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	09 Oct 2020 16:16:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	09 Oct 2020 16:15:57
User opened query 'Per CDM : Kindly remove the unit for temperature, Thanks' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 07:03:34
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 07:03:34
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:27:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:26:54

FDA-CBER-2022-1614-0192189

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:15:47
User entered '36.7' C	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:22

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:47:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:26:54
User entered 'Oral (Oral)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:22

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:47:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:22

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:47:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:26:54
User entered '62'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:22

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered 'bpm'	System	17 Aug 2020 19:26:22

FDA-CBER-2022-1614-0192194

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:47:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:26:54
User entered '14'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:22

FDA-CBER-2022-1614-0192195

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered 'breaths/min'	System	17 Aug 2020 19:26:22

FDA-CBER-2022-1614-0192196

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:47:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:26:54
User entered '142'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:22

FDA-CBER-2022-1614-0192197

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered 'mmHg'	System	17 Aug 2020 19:26:22

FDA-CBER-2022-1614-0192198

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:47:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:26:54
User entered '80'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:22

FDA-CBER-2022-1614-0192199

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User entered 'mmHg'	System	17 Aug 2020 19:26:22

FDA-CBER-2022-1614-0192200

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03

FDA-CBER-2022-1614-0192201

US3042210
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03

FDA-CBER-2022-1614-0192202

US3042210
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 14:58:46
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:48:14
User entered 'No (N)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	22 Sep 2020 16:01:02
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:28

US3042210
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 14:58:46
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:48:14
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 16:01:02
User entered empty; reason for change Data Entry Error	Jamie Thompson (b) (4) (b) (4)	22 Sep 2020 16:01:02
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	15 Sep 2020 13:16:15
User entered '17 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:28

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46

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) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

FDA-CBER-2022-1614-0192207

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

FDA-CBER-2022-1614-0192208

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46

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) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

FDA-CBER-2022-1614-0192216

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

FDA-CBER-2022-1614-0192217

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

FDA-CBER-2022-1614-0192218

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

FDA-CBER-2022-1614-0192219

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46

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) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

FDA-CBER-2022-1614-0192220

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46

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) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

FDA-CBER-2022-1614-0192222

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered '1'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

FDA-CBER-2022-1614-0192223

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

FDA-CBER-2022-1614-0192224

US3042210
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:58:46
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:03
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:19
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:47

FDA-CBER-2022-1614-0192225

US3042210
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:39
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:56

FDA-CBER-2022-1614-0192226

US3042210
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:39
User entered '17 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:56

FDA-CBER-2022-1614-0192227

US3042210
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:39
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:26:56

US3042210
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'VISIT1'	System	17 Aug 2020 19:26:56

FDA-CBER-2022-1614-0192229

US3042210
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:58:46
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:52
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 14:54:55

FDA-CBER-2022-1614-0192230

US3042210
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:58:46
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:52
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:59:03
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:59:02
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 14:54:55
User entered '104611' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 14:54:55

FDA-CBER-2022-1614-0192231

US3042210
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:58:46
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:52
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 14:54:55

FDA-CBER-2022-1614-0192232

US3042210

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:58:46

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) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:03

US3042210
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:58:46

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) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:03

FDA-CBER-2022-1614-0192234

US3042210
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:58:46
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:03

FDA-CBER-2022-1614-0192235

US3042210
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:58:46
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:03

FDA-CBER-2022-1614-0192236

US3042210
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:58:46
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:03

FDA-CBER-2022-1614-0192237

US3042210
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:58:46
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:52
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:40:27
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'ENTRY UPDATED ' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	29 Oct 2020 17:40:57
User entered 'No (N)'	Rylea Gulick (b) (4)	29 Oct 2020 17:40:53
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:29:59
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:22:38
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:37:40

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:58:46
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, “ND” should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:55:26
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, “ND” should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:41:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:41:16
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, “ND” should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 03:52:12
User entered '193.0' cm	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:58:46
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:41:16
User entered '87.1' kg	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:58:46
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, “ND” should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:55:26
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, “ND” should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:41:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:41:16
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, “ND” should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 03:52:12
User entered '193.0' cm	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:58:46
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:41:16
User entered '87.1' kg	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User accepted default value 'Pre-Dose (PREDOSE)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192243

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192244

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered '17 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192245

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered '09:20'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192246

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered '17 Aug 2020 09:20'	(b) (4), (b) (6) System	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192247

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered '36.7' C	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192248

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered 'Oral (Oral)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192249

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192250

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered '62'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192251

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'bpm'	(b) (4), (b) (6) System	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192252

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered '14'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192253

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'breaths/min'	(b) (4), (b) (6) System	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192254

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered '142'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192255

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'mmHg'	(b) (4), (b) (6) System	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192256

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered '80'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192257

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'mmHg'	(b) (4), (b) (6) System	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192258

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:58:46
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, “ND” should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:55:26
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, “ND” should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:41:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:41:16
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, “ND” should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 03:52:12
User entered '193.0' cm	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:58:46
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:41:16
User entered '87.1' kg	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User accepted default value 'Post-Dose (POSTDOSE)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192261

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192262

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered '17 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192263

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 09:00:10
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 PROTOCOL, SUBJECT ONLY NEEDS TO WAIT 30 MINUTES AFTER VACCINATION BEFORE POST DOSE VITALS ARE TAKEN' (Site from System).	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:28:13
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	17 Aug 2020 19:27:50
User entered '10:55'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192264

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered '17 Aug 2020 10:55'	(b) (4), (b) (6) System	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192265

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered '36.5' C	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192266

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered 'Oral (Oral)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192267

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered '53'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192269

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'bpm'	(b) (4), (b) (6) System	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192270

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered '14'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192271

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'breaths/min'	(b) (4), (b) (6) System	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192272

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered '138'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'mmHg'	(b) (4), (b) (6) System	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192274

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:21
User entered '88'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192275

US3042210
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'mmHg'	(b) (4), (b) (6) System	17 Aug 2020 19:27:50

FDA-CBER-2022-1614-0192276

US3042210
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 14:58:46
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:29:04
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:28:19

FDA-CBER-2022-1614-0192277

US3042210
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 14:58:46
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:29:04
User entered '17 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:28:19

FDA-CBER-2022-1614-0192278

US3042210
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:29:21
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192279

US3042210
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:29:21
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192280

US3042210
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:58:46

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) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:29:21
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192281

US3042210
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192282

US3042210
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:29:21
User entered '17 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192283

US3042210
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:29:21
User entered '10:18'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 15:21:08

US3042210
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered '17 Aug 2020 10:18'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192285

US3042210
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:29:21
User entered 'Left Arm (LEFT ARM)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 15:21:08

US3042210
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:29:21
User entered 'ONCE'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192287

US3042210
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192288

US3042210
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:29:39
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:28:40

US3042210
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:29:39
User entered '17 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:28:40

US3042210
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:29:39
User entered '09:47'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:28:40

US3042210
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered '17 Aug 2020 09:47'	System	17 Aug 2020 19:28:40

US3042210
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 14:58:46
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:30:01
User entered '17 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:28:56

FDA-CBER-2022-1614-0192293

US3042210
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:58:46
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:28:56

FDA-CBER-2022-1614-0192294

US3042210
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:58:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:30:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:28:56

US3042210
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:58:46
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:30:01
User entered '09:35'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:28:56

FDA-CBER-2022-1614-0192296

US3042210
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:58:46
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered '17 Aug 2020 09:35'	(b) (4), (b) (6) System	17 Aug 2020 19:28:56

FDA-CBER-2022-1614-0192297

US3042210
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:58:46
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:28:56

US3042210
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:58:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:30:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:28:56

US3042210
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:58:46
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:30:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:28:56

US3042210
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:58:46
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered empty.	(b) (4), (b) (6) System	17 Aug 2020 19:28:56

FDA-CBER-2022-1614-0192301

US3042210
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:30:22
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:28:58

FDA-CBER-2022-1614-0192302

US3042210
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered '1'	System	17 Aug 2020 19:28:58

FDA-CBER-2022-1614-0192303

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192304

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T10:51:45', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '1aae364f-69a6-45c7-b336-40f192895d3c'	System	17 Aug 2020 15:52:47
User entered 'Yes (Y)'	System	17 Aug 2020 15:52:47

FDA-CBER-2022-1614-0192305

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T10:52:22', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '1aae364f-69a6-45c7-b336-40f192895d3c'	System	17 Aug 2020 15:52:47
User entered '97.7'	System	17 Aug 2020 15:52:47

FDA-CBER-2022-1614-0192306

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T10:52:37', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '1aae364f-69a6-45c7-b336-40f192895d3c'	System	17 Aug 2020 15:52:47
User entered 'No (N)'	System	17 Aug 2020 15:52:47

FDA-CBER-2022-1614-0192307

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T10:52:44', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '1aae364f-69a6-45c7-b336-40f192895d3c'	System	17 Aug 2020 15:52:47
User entered '17 Aug 2020 10:52'	System	17 Aug 2020 15:52:47

FDA-CBER-2022-1614-0192308

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '17 Aug 2020 10:38'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192309

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '17 Aug 2020 13:08'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192310

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192311

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T19:24:36', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'd6150480-05e6-42d5-b2cc-9010cf7fc6de'	System	18 Aug 2020 00:25:04
User entered 'Yes (Y)'	System	18 Aug 2020 00:25:04

FDA-CBER-2022-1614-0192312

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T19:24:43', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'd6150480-05e6-42d5-b2cc-9010cf7fc6de'	System	18 Aug 2020 00:25:04
User entered '97.7'	System	18 Aug 2020 00:25:04

FDA-CBER-2022-1614-0192313

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T19:24:49', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'd6150480-05e6-42d5-b2cc-9010cf7fc6de'	System	18 Aug 2020 00:25:04
User entered 'No (N)'	System	18 Aug 2020 00:25:04

FDA-CBER-2022-1614-0192314

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T19:25:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'd6150480-05e6-42d5-b2cc-9010cf7fc6de'	System	18 Aug 2020 00:25:04
User entered '17 Aug 2020 19:25'	System	18 Aug 2020 00:25:04

FDA-CBER-2022-1614-0192315

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '17 Aug 2020 14:03'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192316

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192317

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 2'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192318

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:58:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-18T19:40:26', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'd24536e6-f78c-423c-ab14-6073b926407b'	System	19 Aug 2020 00:40:49
User entered 'Yes (Y)'	System	19 Aug 2020 00:40:49

FDA-CBER-2022-1614-0192319

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:58:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-18T19:40:34', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'd24536e6-f78c-423c-ab14-6073b926407b'	System	19 Aug 2020 00:40:49
User entered '98.2'	System	19 Aug 2020 00:40:49

FDA-CBER-2022-1614-0192320

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:58:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-18T19:40:37', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'd24536e6-f78c-423c-ab14-6073b926407b'	System	19 Aug 2020 00:40:49
User entered 'No (N)'	System	19 Aug 2020 00:40:49

FDA-CBER-2022-1614-0192321

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-18T19:40:44', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'd24536e6-f78c-423c-ab14-6073b926407b'	System	19 Aug 2020 00:40:49
User entered '18 Aug 2020 19:40'	System	19 Aug 2020 00:40:49

FDA-CBER-2022-1614-0192322

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192323

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192324

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 3'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192325

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:58:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-19T19:33:20', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'e1bf165f-8c5a-44b3-a4cc-5ed37b2c0ca9'	System	20 Aug 2020 00:33:38
User entered 'Yes (Y)'	System	20 Aug 2020 00:33:38

FDA-CBER-2022-1614-0192326

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:58:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-19T19:33:25', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'e1bf165f-8c5a-44b3-a4cc-5ed37b2c0ca9'	System	20 Aug 2020 00:33:38
User entered '98.6'	System	20 Aug 2020 00:33:38

FDA-CBER-2022-1614-0192327

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:58:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-19T19:33:28', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'e1bf165f-8c5a-44b3-a4cc-5ed37b2c0ca9'	System	20 Aug 2020 00:33:38
User entered 'No (N)'	System	20 Aug 2020 00:33:38

FDA-CBER-2022-1614-0192328

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-19T19:33:34', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'e1bf165f-8c5a-44b3-a4cc-5ed37b2c0ca9'	System	20 Aug 2020 00:33:38
User entered '19 Aug 2020 19:33'	System	20 Aug 2020 00:33:38

FDA-CBER-2022-1614-0192329

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192330

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192331

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 4'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192332

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:58:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192333

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:58:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192334

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:58:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192335

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:58:46
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192336

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:58:46
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192337

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192338

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192339

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192340

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 5'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192341

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:58:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-21T20:41:01', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '0337a9ac-52a6-43e6-b328-f812486efb4c'	System	22 Aug 2020 01:41:17
User entered 'Yes (Y)'	System	22 Aug 2020 01:41:17

FDA-CBER-2022-1614-0192342

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:58:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-21T20:41:07', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '0337a9ac-52a6-43e6-b328-f812486efb4c'	System	22 Aug 2020 01:41:17
User entered '97.9'	System	22 Aug 2020 01:41:17

FDA-CBER-2022-1614-0192343

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:58:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-21T20:41:10', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '0337a9ac-52a6-43e6-b328-f812486efb4c'	System	22 Aug 2020 01:41:17
User entered 'No (N)'	System	22 Aug 2020 01:41:17

FDA-CBER-2022-1614-0192344

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-21T20:41:14', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '0337a9ac-52a6-43e6-b328-f812486efb4c'	System	22 Aug 2020 01:41:17
User entered '21 Aug 2020 20:41'	System	22 Aug 2020 01:41:17

FDA-CBER-2022-1614-0192345

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192346

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192347

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 6'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192348

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:58:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-22T19:36:11', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'dee77221-555d-4a30-be93-18f1c0653dba'	System	23 Aug 2020 00:36:35
User entered 'Yes (Y)'	System	23 Aug 2020 00:36:35

FDA-CBER-2022-1614-0192349

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:58:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-22T19:36:20', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'dee77221-555d-4a30-be93-18f1c0653dba'	System	23 Aug 2020 00:36:35
User entered '97.8'	System	23 Aug 2020 00:36:35

FDA-CBER-2022-1614-0192350

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:58:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-22T19:36:23', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'dee77221-555d-4a30-be93-18f1c0653dba'	System	23 Aug 2020 00:36:35
User entered 'No (N)'	System	23 Aug 2020 00:36:35

FDA-CBER-2022-1614-0192351

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-22T19:36:33', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'dee77221-555d-4a30-be93-18f1c0653dba'	System	23 Aug 2020 00:36:35
User entered '22 Aug 2020 19:36'	System	23 Aug 2020 00:36:35

FDA-CBER-2022-1614-0192352

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192353

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192354

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 7'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192355

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:58:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-23T20:40:40', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '15a8ad68-a3c2-46ad-86d5-9ce11bb3ed38'	System	24 Aug 2020 01:41:02
User entered 'Yes (Y)'	System	24 Aug 2020 01:41:02

FDA-CBER-2022-1614-0192356

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:58:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-23T20:40:54', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '15a8ad68-a3c2-46ad-86d5-9ce11bb3ed38'	System	24 Aug 2020 01:41:02
User entered '98.3'	System	24 Aug 2020 01:41:02

FDA-CBER-2022-1614-0192357

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:58:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-23T20:40:57', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '15a8ad68-a3c2-46ad-86d5-9ce11bb3ed38'	System	24 Aug 2020 01:41:02
User entered 'No (N)'	System	24 Aug 2020 01:41:02

FDA-CBER-2022-1614-0192358

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-23T20:40:59', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '15a8ad68-a3c2-46ad-86d5-9ce11bb3ed38'	System	24 Aug 2020 01:41:02
User entered '23 Aug 2020 20:40'	System	24 Aug 2020 01:41:02

FDA-CBER-2022-1614-0192359

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192360

US3042210
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192361

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192362

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T10:53:32', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'cf6665f2-b1ef-4573-ab6b-a35380011046'	System	17 Aug 2020 15:53:55
User entered 'None (1)'	System	17 Aug 2020 15:53:55

FDA-CBER-2022-1614-0192363

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T10:53:37', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'cf6665f2-b1ef-4573-ab6b-a35380011046'	System	17 Aug 2020 15:53:55
User entered 'No (N)'	System	17 Aug 2020 15:53:55

FDA-CBER-2022-1614-0192364

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T10:53:42', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'cf6665f2-b1ef-4573-ab6b-a35380011046'	System	17 Aug 2020 15:53:55
User entered 'No (N)'	System	17 Aug 2020 15:53:55

FDA-CBER-2022-1614-0192365

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T10:53:48', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'cf6665f2-b1ef-4573-ab6b-a35380011046'	System	17 Aug 2020 15:53:55
User entered 'None (1)'	System	17 Aug 2020 15:53:55

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T10:53:52', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'cf6665f2-b1ef-4573-ab6b-a35380011046'	System	17 Aug 2020 15:53:55
User entered '17 Aug 2020 10:53'	System	17 Aug 2020 15:53:55

FDA-CBER-2022-1614-0192367

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '17 Aug 2020 10:38'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192368

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '17 Aug 2020 13:08'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192369

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 15:21:08

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T19:25:33', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '47d1b56c-8e2f-4288-bf6f-bcbaffa4f285'	System	18 Aug 2020 00:26:05
User entered 'None (1)'	System	18 Aug 2020 00:26:05

FDA-CBER-2022-1614-0192371

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T19:25:37', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '47d1b56c-8e2f-4288-bf6f-bcbaffa4f285'	System	18 Aug 2020 00:26:05
User entered 'No (N)'	System	18 Aug 2020 00:26:05

FDA-CBER-2022-1614-0192372

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T19:25:40', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '47d1b56c-8e2f-4288-bf6f-bcbaffa4f285'	System	18 Aug 2020 00:26:05
User entered 'No (N)'	System	18 Aug 2020 00:26:05

FDA-CBER-2022-1614-0192373

US3042210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T19:25:45', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '47d1b56c-8e2f-4288-bf6f-bcbaffa4f285'	System	18 Aug 2020 00:26:05
User entered 'None (1)'	System	18 Aug 2020 00:26:05

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T19:26:01', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '47d1b56c-8e2f-4288-bf6f-bcbaffa4f285'	System	18 Aug 2020 00:26:05
User entered '17 Aug 2020 19:26'	System	18 Aug 2020 00:26:05

FDA-CBER-2022-1614-0192375

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '17 Aug 2020 14:03'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192376

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192377

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 2'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192378

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:58:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-18T19:40:48', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'de061602-e048-4277-b6cd-b0b0c6f08201'	System	19 Aug 2020 00:41:07
User entered 'None (1)'	System	19 Aug 2020 00:41:07

FDA-CBER-2022-1614-0192379

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:58:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-18T19:40:52', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'de061602-e048-4277-b6cd-b0b0c6f08201'	System	19 Aug 2020 00:41:07
User entered 'No (N)'	System	19 Aug 2020 00:41:07

FDA-CBER-2022-1614-0192380

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:58:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-18T19:40:54', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'de061602-e048-4277-b6cd-b0b0c6f08201'	System	19 Aug 2020 00:41:07
User entered 'No (N)'	System	19 Aug 2020 00:41:07

FDA-CBER-2022-1614-0192381

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:58:46
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-18T19:40:57', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'de061602-e048-4277-b6cd-b0b0c6f08201'	System	19 Aug 2020 00:41:07
User entered 'None (1)'	System	19 Aug 2020 00:41:07

FDA-CBER-2022-1614-0192382

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-18T19:41:03', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'de061602-e048-4277-b6cd-b0b0c6f08201'	System	19 Aug 2020 00:41:07
User entered '18 Aug 2020 19:41'	System	19 Aug 2020 00:41:07

FDA-CBER-2022-1614-0192383

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192384

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192385

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 3'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192386

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:58:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-19T19:33:39', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'f479f4bd-4d1a-4a71-9a6c-063ea3a3269e'	System	20 Aug 2020 00:33:56
User entered 'None (1)'	System	20 Aug 2020 00:33:56

FDA-CBER-2022-1614-0192387

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:58:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-19T19:33:42', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'f479f4bd-4d1a-4a71-9a6c-063ea3a3269e'	System	20 Aug 2020 00:33:56
User entered 'No (N)'	System	20 Aug 2020 00:33:56

FDA-CBER-2022-1614-0192388

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:58:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-19T19:33:44', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'f479f4bd-4d1a-4a71-9a6c-063ea3a3269e'	System	20 Aug 2020 00:33:56
User entered 'No (N)'	System	20 Aug 2020 00:33:56

FDA-CBER-2022-1614-0192389

US3042210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-19T19:33:46', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'f479f4bd-4d1a-4a71-9a6c-063ea3a3269e'	System	20 Aug 2020 00:33:56
User entered 'None (1)'	System	20 Aug 2020 00:33:56

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-19T19:33:53', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'f479f4bd-4d1a-4a71-9a6c-063ea3a3269e'	System	20 Aug 2020 00:33:56
User entered '19 Aug 2020 19:33'	System	20 Aug 2020 00:33:56

FDA-CBER-2022-1614-0192391

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192392

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192393

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 4'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192394

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192395

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192396

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192397

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192398

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46

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) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192399

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192400

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192401

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192402

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192403

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 5'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192404

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:58:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-21T20:41:17', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '0a437f4e-8e89-4481-bf9d-ec4d99f73a31'	System	22 Aug 2020 01:41:30
User entered 'None (1)'	System	22 Aug 2020 01:41:30

FDA-CBER-2022-1614-0192405

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:58:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-21T20:41:20', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '0a437f4e-8e89-4481-bf9d-ec4d99f73a31'	System	22 Aug 2020 01:41:30
User entered 'No (N)'	System	22 Aug 2020 01:41:30

FDA-CBER-2022-1614-0192406

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:58:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-21T20:41:22', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '0a437f4e-8e89-4481-bf9d-ec4d99f73a31'	System	22 Aug 2020 01:41:30
User entered 'No (N)'	System	22 Aug 2020 01:41:30

FDA-CBER-2022-1614-0192407

US3042210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-21T20:41:24', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '0a437f4e-8e89-4481-bf9d-ec4d99f73a31'	System	22 Aug 2020 01:41:30
User entered 'None (1)'	System	22 Aug 2020 01:41:30

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-21T20:41:27', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '0a437f4e-8e89-4481-bf9d-ec4d99f73a31'	System	22 Aug 2020 01:41:30
User entered '21 Aug 2020 20:41'	System	22 Aug 2020 01:41:30

FDA-CBER-2022-1614-0192409

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192410

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192411

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 6'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192412

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:58:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-22T19:36:38', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '349d2cb5-24dc-4f41-8db1-97cf5344472d'	System	23 Aug 2020 00:36:59
User entered 'None (1)'	System	23 Aug 2020 00:36:59

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:58:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-22T19:36:45', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '349d2cb5-24dc-4f41-8db1-97cf5344472d'	System	23 Aug 2020 00:36:59
User entered 'No (N)'	System	23 Aug 2020 00:36:59

FDA-CBER-2022-1614-0192414

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:58:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-22T19:36:46', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '349d2cb5-24dc-4f41-8db1-97cf5344472d'	System	23 Aug 2020 00:36:59
User entered 'No (N)'	System	23 Aug 2020 00:36:59

FDA-CBER-2022-1614-0192415

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:58:46
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-22T19:36:48', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '349d2cb5-24dc-4f41-8db1-97cf5344472d'	System	23 Aug 2020 00:36:59
User entered 'None (1)'	System	23 Aug 2020 00:36:59

FDA-CBER-2022-1614-0192416

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-22T19:36:56', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '349d2cb5-24dc-4f41-8db1-97cf5344472d'	System	23 Aug 2020 00:36:59
User entered '22 Aug 2020 19:36'	System	23 Aug 2020 00:36:59

FDA-CBER-2022-1614-0192417

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192418

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192419

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 7'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192420

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:58:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-23T20:41:03', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '6aef27ce-34ca-4e23-b8bf-ca9b2c676672'	System	24 Aug 2020 01:41:18
User entered 'None (1)'	System	24 Aug 2020 01:41:18

FDA-CBER-2022-1614-0192421

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:58:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-23T20:41:05', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '6aef27ce-34ca-4e23-b8bf-ca9b2c676672'	System	24 Aug 2020 01:41:18
User entered 'No (N)'	System	24 Aug 2020 01:41:18

FDA-CBER-2022-1614-0192422

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:58:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-23T20:41:07', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '6aef27ce-34ca-4e23-b8bf-ca9b2c676672'	System	24 Aug 2020 01:41:18
User entered 'No (N)'	System	24 Aug 2020 01:41:18

FDA-CBER-2022-1614-0192423

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:58:46
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-23T20:41:10', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '6aef27ce-34ca-4e23-b8bf-ca9b2c676672'	System	24 Aug 2020 01:41:18
User entered 'None (1)'	System	24 Aug 2020 01:41:18

FDA-CBER-2022-1614-0192424

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-23T20:41:15', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '6aef27ce-34ca-4e23-b8bf-ca9b2c676672'	System	24 Aug 2020 01:41:18
User entered '23 Aug 2020 20:41'	System	24 Aug 2020 01:41:18

FDA-CBER-2022-1614-0192425

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192426

US3042210
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192427

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 15:21:08

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T10:54:05', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'a928fd7b-c885-47a7-9206-d594fa8c4838'	System	17 Aug 2020 15:54:41
User entered 'None (0)'	System	17 Aug 2020 15:54:41

FDA-CBER-2022-1614-0192429

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T10:54:10', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'a928fd7b-c885-47a7-9206-d594fa8c4838'	System	17 Aug 2020 15:54:41
User entered 'None (0)'	System	17 Aug 2020 15:54:41

FDA-CBER-2022-1614-0192430

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T10:54:12', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'a928fd7b-c885-47a7-9206-d594fa8c4838'	System	17 Aug 2020 15:54:41
User entered 'None (0)'	System	17 Aug 2020 15:54:41

FDA-CBER-2022-1614-0192431

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T10:54:22', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'a928fd7b-c885-47a7-9206-d594fa8c4838'	System	17 Aug 2020 15:54:41
User entered 'None (0)'	System	17 Aug 2020 15:54:41

FDA-CBER-2022-1614-0192432

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T10:54:26', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'a928fd7b-c885-47a7-9206-d594fa8c4838'	System	17 Aug 2020 15:54:41
User entered 'None (0)'	System	17 Aug 2020 15:54:41

FDA-CBER-2022-1614-0192433

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T10:54:29', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'a928fd7b-c885-47a7-9206-d594fa8c4838'	System	17 Aug 2020 15:54:41
User entered 'None (0)'	System	17 Aug 2020 15:54:41

FDA-CBER-2022-1614-0192434

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T10:54:34', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'a928fd7b-c885-47a7-9206-d594fa8c4838'	System	17 Aug 2020 15:54:41
User entered 'No (N)'	System	17 Aug 2020 15:54:41

FDA-CBER-2022-1614-0192435

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T10:54:38', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'a928fd7b-c885-47a7-9206-d594fa8c4838'	System	17 Aug 2020 15:54:41
User entered '17 Aug 2020 10:54'	System	17 Aug 2020 15:54:41

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '17 Aug 2020 10:38'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192437

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '17 Aug 2020 13:08'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192438

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192439

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T19:26:13', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '30959663-31e7-4145-9b25-12b5e368b8ec'	System	18 Aug 2020 00:27:01
User entered 'No interference with activity (1)'	System	18 Aug 2020 00:27:01

FDA-CBER-2022-1614-0192440

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T19:26:27', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '30959663-31e7-4145-9b25-12b5e368b8ec'	System	18 Aug 2020 00:27:01
User entered 'No interference with activity (1)'	System	18 Aug 2020 00:27:01

FDA-CBER-2022-1614-0192441

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T19:26:32', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '30959663-31e7-4145-9b25-12b5e368b8ec'	System	18 Aug 2020 00:27:01
User entered 'None (0)'	System	18 Aug 2020 00:27:01

FDA-CBER-2022-1614-0192442

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T19:26:35', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '30959663-31e7-4145-9b25-12b5e368b8ec'	System	18 Aug 2020 00:27:01
User entered 'None (0)'	System	18 Aug 2020 00:27:01

FDA-CBER-2022-1614-0192443

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T19:26:38', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '30959663-31e7-4145-9b25-12b5e368b8ec'	System	18 Aug 2020 00:27:01
User entered 'None (0)'	System	18 Aug 2020 00:27:01

FDA-CBER-2022-1614-0192444

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T19:26:41', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '30959663-31e7-4145-9b25-12b5e368b8ec'	System	18 Aug 2020 00:27:01
User entered 'None (0)'	System	18 Aug 2020 00:27:01

FDA-CBER-2022-1614-0192445

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T19:26:47', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '30959663-31e7-4145-9b25-12b5e368b8ec'	System	18 Aug 2020 00:27:01
User entered 'No (N)'	System	18 Aug 2020 00:27:01

FDA-CBER-2022-1614-0192446

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-17T19:26:58', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '30959663-31e7-4145-9b25-12b5e368b8ec'	System	18 Aug 2020 00:27:01
User entered '17 Aug 2020 19:26'	System	18 Aug 2020 00:27:01

FDA-CBER-2022-1614-0192447

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '17 Aug 2020 14:03'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192448

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192449

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 2'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192450

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-18T19:41:09', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '6e0d9329-adfa-465b-b029-5a0ffa1ca5ec'	System	19 Aug 2020 00:41:34
User entered 'None (0)'	System	19 Aug 2020 00:41:34

FDA-CBER-2022-1614-0192451

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-18T19:41:10', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '6e0d9329-adfa-465b-b029-5a0ffa1ca5ec'	System	19 Aug 2020 00:41:34
User entered 'None (0)'	System	19 Aug 2020 00:41:34

FDA-CBER-2022-1614-0192452

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-18T19:41:13', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '6e0d9329-adfa-465b-b029-5a0ffa1ca5ec'	System	19 Aug 2020 00:41:34
User entered 'None (0)'	System	19 Aug 2020 00:41:34

FDA-CBER-2022-1614-0192453

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-18T19:41:15', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '6e0d9329-adfa-465b-b029-5a0ffa1ca5ec'	System	19 Aug 2020 00:41:34
User entered 'None (0)'	System	19 Aug 2020 00:41:34

FDA-CBER-2022-1614-0192454

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-18T19:41:17', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '6e0d9329-adfa-465b-b029-5a0ffa1ca5ec'	System	19 Aug 2020 00:41:34
User entered 'None (0)'	System	19 Aug 2020 00:41:34

FDA-CBER-2022-1614-0192455

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-18T19:41:18', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '6e0d9329-adfa-465b-b029-5a0ffa1ca5ec'	System	19 Aug 2020 00:41:34
User entered 'None (0)'	System	19 Aug 2020 00:41:34

FDA-CBER-2022-1614-0192456

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-18T19:41:23', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '6e0d9329-adfa-465b-b029-5a0ffa1ca5ec'	System	19 Aug 2020 00:41:34
User entered 'No (N)'	System	19 Aug 2020 00:41:34

FDA-CBER-2022-1614-0192457

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-18T19:41:29', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '6e0d9329-adfa-465b-b029-5a0ffa1ca5ec'	System	19 Aug 2020 00:41:34
User entered '18 Aug 2020 19:41'	System	19 Aug 2020 00:41:34

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192459

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192460

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 3'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192461

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-19T19:33:57', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '4bc5d537-e62a-422e-a49c-a96d041935f0'	System	20 Aug 2020 00:34:22
User entered 'None (0)'	System	20 Aug 2020 00:34:22

FDA-CBER-2022-1614-0192462

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-19T19:33:59', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '4bc5d537-e62a-422e-a49c-a96d041935f0'	System	20 Aug 2020 00:34:22
User entered 'None (0)'	System	20 Aug 2020 00:34:22

FDA-CBER-2022-1614-0192463

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-19T19:34:01', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '4bc5d537-e62a-422e-a49c-a96d041935f0'	System	20 Aug 2020 00:34:22
User entered 'None (0)'	System	20 Aug 2020 00:34:22

FDA-CBER-2022-1614-0192464

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-19T19:34:03', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '4bc5d537-e62a-422e-a49c-a96d041935f0'	System	20 Aug 2020 00:34:22
User entered 'None (0)'	System	20 Aug 2020 00:34:22

FDA-CBER-2022-1614-0192465

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-19T19:34:05', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '4bc5d537-e62a-422e-a49c-a96d041935f0'	System	20 Aug 2020 00:34:22
User entered 'None (0)'	System	20 Aug 2020 00:34:22

FDA-CBER-2022-1614-0192466

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-19T19:34:07', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '4bc5d537-e62a-422e-a49c-a96d041935f0'	System	20 Aug 2020 00:34:22
User entered 'None (0)'	System	20 Aug 2020 00:34:22

FDA-CBER-2022-1614-0192467

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-19T19:34:11', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '4bc5d537-e62a-422e-a49c-a96d041935f0'	System	20 Aug 2020 00:34:22
User entered 'No (N)'	System	20 Aug 2020 00:34:22

FDA-CBER-2022-1614-0192468

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-19T19:34:19', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '4bc5d537-e62a-422e-a49c-a96d041935f0'	System	20 Aug 2020 00:34:22
User entered '19 Aug 2020 19:34'	System	20 Aug 2020 00:34:22

FDA-CBER-2022-1614-0192469

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192470

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192471

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 4'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192472

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192473

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192474

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192475

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192476

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192477

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192478

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192479

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28

FDA-CBER-2022-1614-0192480

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192481

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192482

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 5'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192483

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-21T20:41:31', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '2078738d-d758-462f-b72b-e1eb18751a05'	System	22 Aug 2020 01:41:53
User entered 'None (0)'	System	22 Aug 2020 01:41:53

FDA-CBER-2022-1614-0192484

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-21T20:41:32', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '2078738d-d758-462f-b72b-e1eb18751a05'	System	22 Aug 2020 01:41:53
User entered 'None (0)'	System	22 Aug 2020 01:41:53

FDA-CBER-2022-1614-0192485

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-21T20:41:34', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '2078738d-d758-462f-b72b-e1eb18751a05'	System	22 Aug 2020 01:41:53
User entered 'None (0)'	System	22 Aug 2020 01:41:53

FDA-CBER-2022-1614-0192486

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-21T20:41:35', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '2078738d-d758-462f-b72b-e1eb18751a05'	System	22 Aug 2020 01:41:53
User entered 'None (0)'	System	22 Aug 2020 01:41:53

FDA-CBER-2022-1614-0192487

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-21T20:41:37', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '2078738d-d758-462f-b72b-e1eb18751a05'	System	22 Aug 2020 01:41:53
User entered 'None (0)'	System	22 Aug 2020 01:41:53

FDA-CBER-2022-1614-0192488

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-21T20:41:39', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '2078738d-d758-462f-b72b-e1eb18751a05'	System	22 Aug 2020 01:41:53
User entered 'None (0)'	System	22 Aug 2020 01:41:53

FDA-CBER-2022-1614-0192489

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-21T20:41:43', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '2078738d-d758-462f-b72b-e1eb18751a05'	System	22 Aug 2020 01:41:53
User entered 'No (N)'	System	22 Aug 2020 01:41:53

FDA-CBER-2022-1614-0192490

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-21T20:41:49', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '2078738d-d758-462f-b72b-e1eb18751a05'	System	22 Aug 2020 01:41:53
User entered '21 Aug 2020 20:41'	System	22 Aug 2020 01:41:53

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192492

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192493

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 6'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192494

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-22T19:37:04', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '803af0b3-1304-43f9-bd4a-c78254ac3c67'	System	23 Aug 2020 00:37:25
User entered 'None (0)'	System	23 Aug 2020 00:37:25

FDA-CBER-2022-1614-0192495

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-22T19:37:05', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '803af0b3-1304-43f9-bd4a-c78254ac3c67'	System	23 Aug 2020 00:37:25
User entered 'None (0)'	System	23 Aug 2020 00:37:25

FDA-CBER-2022-1614-0192496

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-22T19:37:08', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '803af0b3-1304-43f9-bd4a-c78254ac3c67'	System	23 Aug 2020 00:37:25
User entered 'None (0)'	System	23 Aug 2020 00:37:25

FDA-CBER-2022-1614-0192497

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-22T19:37:09', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '803af0b3-1304-43f9-bd4a-c78254ac3c67'	System	23 Aug 2020 00:37:25
User entered 'None (0)'	System	23 Aug 2020 00:37:25

FDA-CBER-2022-1614-0192498

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-22T19:37:11', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '803af0b3-1304-43f9-bd4a-c78254ac3c67'	System	23 Aug 2020 00:37:25
User entered 'None (0)'	System	23 Aug 2020 00:37:25

FDA-CBER-2022-1614-0192499

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-22T19:37:13', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '803af0b3-1304-43f9-bd4a-c78254ac3c67'	System	23 Aug 2020 00:37:25
User entered 'None (0)'	System	23 Aug 2020 00:37:25

FDA-CBER-2022-1614-0192500

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-22T19:37:17', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '803af0b3-1304-43f9-bd4a-c78254ac3c67'	System	23 Aug 2020 00:37:25
User entered 'No (N)'	System	23 Aug 2020 00:37:25

FDA-CBER-2022-1614-0192501

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-22T19:37:22', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '803af0b3-1304-43f9-bd4a-c78254ac3c67'	System	23 Aug 2020 00:37:25
User entered '22 Aug 2020 19:37'	System	23 Aug 2020 00:37:25

FDA-CBER-2022-1614-0192502

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192503

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192504

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 7'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192505

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-23T20:41:19', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '7ddf5f03-0a3e-4f5e-be78-112f1b143c83'	System	24 Aug 2020 01:41:46
User entered 'None (0)'	System	24 Aug 2020 01:41:46

FDA-CBER-2022-1614-0192506

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-23T20:41:20', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '7ddf5f03-0a3e-4f5e-be78-112f1b143c83'	System	24 Aug 2020 01:41:46
User entered 'None (0)'	System	24 Aug 2020 01:41:46

FDA-CBER-2022-1614-0192507

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-23T20:41:22', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '7ddf5f03-0a3e-4f5e-be78-112f1b143c83'	System	24 Aug 2020 01:41:46
User entered 'None (0)'	System	24 Aug 2020 01:41:46

FDA-CBER-2022-1614-0192508

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-23T20:41:24', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '7ddf5f03-0a3e-4f5e-be78-112f1b143c83'	System	24 Aug 2020 01:41:46
User entered 'None (0)'	System	24 Aug 2020 01:41:46

FDA-CBER-2022-1614-0192509

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-23T20:41:26', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '7ddf5f03-0a3e-4f5e-be78-112f1b143c83'	System	24 Aug 2020 01:41:46
User entered 'None (0)'	System	24 Aug 2020 01:41:46

FDA-CBER-2022-1614-0192510

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-23T20:41:28', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '7ddf5f03-0a3e-4f5e-be78-112f1b143c83'	System	24 Aug 2020 01:41:46
User entered 'None (0)'	System	24 Aug 2020 01:41:46

FDA-CBER-2022-1614-0192511

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-23T20:41:34', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '7ddf5f03-0a3e-4f5e-be78-112f1b143c83'	System	24 Aug 2020 01:41:46
User entered 'No (N)'	System	24 Aug 2020 01:41:46

FDA-CBER-2022-1614-0192512

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-08-23T20:41:43', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '7ddf5f03-0a3e-4f5e-be78-112f1b143c83'	System	24 Aug 2020 01:41:46
User entered '23 Aug 2020 20:41'	System	24 Aug 2020 01:41:46

FDA-CBER-2022-1614-0192513

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192514

US3042210
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192515

US3042210
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:50:59
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:36:04
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	26 Aug 2020 15:09:04

FDA-CBER-2022-1614-0192516

US3042210
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:50:59
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:36:04
User entered '24 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	26 Aug 2020 15:09:04

US3042210
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:50:59
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:36:04
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4) (b) (4)	26 Aug 2020 15:09:04

US3042210
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:50:59
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:36:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	26 Aug 2020 15:09:04

FDA-CBER-2022-1614-0192519

US3042210
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:50:59
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:36:11
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	26 Aug 2020 15:09:06

US3042210
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:50:59
User entered '1'	System	26 Aug 2020 15:09:06

FDA-CBER-2022-1614-0192521

US3042210
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:32:43
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 23:45:13

US3042210
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:32:43
User entered '01 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 23:45:13

US3042210
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:32:43
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 23:45:13

US3042210
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:32:43
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 23:45:13

US3042210
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:32:49
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 23:45:15

FDA-CBER-2022-1614-0192526

US3042210
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User entered '1'	System	08 Sep 2020 23:45:15

FDA-CBER-2022-1614-0192527

US3042210
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 02:32:12
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:33:04
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 23:45:22

US3042210
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 02:32:12
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:33:04
User entered '08 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 23:45:22

US3042210
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 02:32:12
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:33:04
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 23:45:22

US3042210
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 02:32:12
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:33:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 23:45:22

FDA-CBER-2022-1614-0192531

US3042210
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 02:32:12
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:33:11
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 23:45:24

US3042210
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:32:12
User entered '1'	(b) (4), (b) (6) System	08 Sep 2020 23:45:24

FDA-CBER-2022-1614-0192533

US3042210
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:36
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:16:15

FDA-CBER-2022-1614-0192534

US3042210
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:36
User entered '14 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:16:15

FDA-CBER-2022-1614-0192535

US3042210
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:36
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:16:15

US3042210
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User entered 'VISIT2'	(b) (4), (b) (6) System	15 Sep 2020 13:16:15

FDA-CBER-2022-1614-0192537

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User accepted default value 'Pre-Dose (PREDOSE)'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192539

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered '14 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192540

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered '17:14'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192541

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User entered '14 Sep 2020 17:14'	(b) (4), (b) (6) System	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192542

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered '36.5' C	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192543

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered 'Oral (Oral)'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192544

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered '61'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192546

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User entered 'bpm'	(b) (4), (b) (6) System	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192547

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered '12'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192548

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192549

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered '138'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192550

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User entered 'mmHg'	(b) (4), (b) (6) System	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192551

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered '88'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192552

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User entered 'mmHg'	(b) (4), (b) (6) System	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192553

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User accepted default value 'Post-Dose (POSTDOSE)'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192554

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192555

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered '14 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192556

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered '18:08'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192557

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User entered '14 Sep 2020 18:08'	(b) (4), (b) (6) System	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192558

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered '36.8' C	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192559

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered 'Oral (Oral)'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192561

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered '64'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192562

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User entered 'bpm'	(b) (4), (b) (6) System	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192563

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered '16'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192564

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192565

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered '140'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192566

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User entered 'mmHg'	(b) (4), (b) (6) System	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192567

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:44
User entered '84'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192568

US3042210
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User entered 'mmHg'	(b) (4), (b) (6) System	15 Sep 2020 13:17:52

FDA-CBER-2022-1614-0192569

US3042210
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:58:46
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:53
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:59

FDA-CBER-2022-1614-0192570

US3042210
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:58:46
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:36:53
User entered '14 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:17:59

FDA-CBER-2022-1614-0192571

US3042210
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:37:05
User entered 'Yes (Y)'	Jessica Knight (b) (4) (b) (4)	14 Sep 2020 22:39:36

US3042210
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:37:05
User entered empty.	Jessica Knight (b) (4) (b) (4)	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192573

US3042210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:46

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) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:37:05
User entered empty.	Jessica Knight (b) (4) (b) (4)	14 Sep 2020 22:39:36

US3042210
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192575

US3042210
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:37:05
User entered '14 Sep 2020'	Jessica Knight (b) (4) (b) (4)	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192576

US3042210
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:37:05
User entered '17:36'	Jessica Knight (b) (4) (b) (4)	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192577

US3042210
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User entered '14 Sep 2020 17:36'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192578

US3042210
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:37:05
User entered 'Left Arm (LEFT ARM)'	Jessica Knight (b) (4) (b) (4)	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192579

US3042210
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	06 Jan 2021 19:37:05
User entered 'ONCE'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192580

US3042210
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192581

US3042210
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:39:28
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:18:11

US3042210
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:39:28
User entered '14 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:18:11

FDA-CBER-2022-1614-0192583

US3042210
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:39:28
User entered '17:22'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:18:11

FDA-CBER-2022-1614-0192584

US3042210
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User entered '14 Sep 2020 17:22'	(b) (4), (b) (6) System	15 Sep 2020 13:18:11

FDA-CBER-2022-1614-0192585

US3042210
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 14:58:46
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:39:56
User entered '14 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:18:21

FDA-CBER-2022-1614-0192586

US3042210
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:58:46
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:18:21

FDA-CBER-2022-1614-0192587

US3042210
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:58:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:39:56
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:18:21

FDA-CBER-2022-1614-0192588

US3042210
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:58:46
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:39:56
User entered '17:17'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:18:21

US3042210
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:58:46
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User entered '14 Sep 2020 17:17'	(b) (4), (b) (6) System	15 Sep 2020 13:18:21

FDA-CBER-2022-1614-0192590

US3042210
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:58:46
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:18:21

FDA-CBER-2022-1614-0192591

US3042210
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:58:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:39:56
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:18:21

FDA-CBER-2022-1614-0192592

US3042210
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:58:46
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:39:56
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:18:21

FDA-CBER-2022-1614-0192593

US3042210
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:58:46
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User entered empty.	(b) (4), (b) (6) System	15 Sep 2020 13:18:21

FDA-CBER-2022-1614-0192594

US3042210
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:10:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:40:32
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 13:18:23

FDA-CBER-2022-1614-0192595

US3042210
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:31
User entered '1'	(b) (4), (b) (6) System	15 Sep 2020 13:18:23

FDA-CBER-2022-1614-0192596

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 22:39:36

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T18:11:22', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '99327df8-ff1c-44be-a33b-0cb21f0f92af'	System	14 Sep 2020 23:11:44
User entered 'Yes (Y)'	System	14 Sep 2020 23:11:44

FDA-CBER-2022-1614-0192598

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T18:11:31', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '99327df8-ff1c-44be-a33b-0cb21f0f92af'	System	14 Sep 2020 23:11:44
User entered '98.2'	System	14 Sep 2020 23:11:44

FDA-CBER-2022-1614-0192599

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T18:11:35', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '99327df8-ff1c-44be-a33b-0cb21f0f92af'	System	14 Sep 2020 23:11:44
User entered 'No (N)'	System	14 Sep 2020 23:11:44

FDA-CBER-2022-1614-0192600

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T18:11:38', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '99327df8-ff1c-44be-a33b-0cb21f0f92af'	System	14 Sep 2020 23:11:44
User entered '14 Sep 2020 18:11'	System	14 Sep 2020 23:11:44

FDA-CBER-2022-1614-0192601

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '14 Sep 2020 17:56'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192602

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '14 Sep 2020 20:26'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192603

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192604

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T21:38:51', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'f1d38a3e-d50d-4514-a9dd-e5c9fbb56b9b'	System	15 Sep 2020 02:39:08
User entered 'Yes (Y)'	System	15 Sep 2020 02:39:08

FDA-CBER-2022-1614-0192605

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T21:38:58', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'f1d38a3e-d50d-4514-a9dd-e5c9fbb56b9b'	System	15 Sep 2020 02:39:08
User entered '98.5'	System	15 Sep 2020 02:39:08

FDA-CBER-2022-1614-0192606

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T21:39:02', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'f1d38a3e-d50d-4514-a9dd-e5c9fbb56b9b'	System	15 Sep 2020 02:39:08
User entered 'No (N)'	System	15 Sep 2020 02:39:08

FDA-CBER-2022-1614-0192607

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T21:39:04', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'f1d38a3e-d50d-4514-a9dd-e5c9fbb56b9b'	System	15 Sep 2020 02:39:08
User entered '14 Sep 2020 21:39'	System	15 Sep 2020 02:39:08

FDA-CBER-2022-1614-0192608

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '14 Sep 2020 21:21'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192609

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192610

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 2'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192611

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:58:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-15T19:50:27', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '9d946467-60b2-4516-9ba9-546d8c5ec4d1'	System	16 Sep 2020 00:50:49
User entered 'Yes (Y)'	System	16 Sep 2020 00:50:49

FDA-CBER-2022-1614-0192612

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:58:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-15T19:50:42', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '9d946467-60b2-4516-9ba9-546d8c5ec4d1'	System	16 Sep 2020 00:50:49
User entered '98.3'	System	16 Sep 2020 00:50:49

FDA-CBER-2022-1614-0192613

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:58:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-15T19:50:45', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '9d946467-60b2-4516-9ba9-546d8c5ec4d1'	System	16 Sep 2020 00:50:49
User entered 'No (N)'	System	16 Sep 2020 00:50:49

FDA-CBER-2022-1614-0192614

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-15T19:50:47', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '9d946467-60b2-4516-9ba9-546d8c5ec4d1'	System	16 Sep 2020 00:50:49
User entered '15 Sep 2020 19:50'	System	16 Sep 2020 00:50:49

FDA-CBER-2022-1614-0192615

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192616

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192617

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 3'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192618

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:58:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-16T21:01:50', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'af4e6ec7-8191-4eb0-89c5-ce0d88b376b2'	System	17 Sep 2020 02:02:06
User entered 'Yes (Y)'	System	17 Sep 2020 02:02:06

FDA-CBER-2022-1614-0192619

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:58:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-16T21:01:56', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'af4e6ec7-8191-4eb0-89c5-ce0d88b376b2'	System	17 Sep 2020 02:02:06
User entered '98.0'	System	17 Sep 2020 02:02:06

FDA-CBER-2022-1614-0192620

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:58:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-16T21:01:59', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'af4e6ec7-8191-4eb0-89c5-ce0d88b376b2'	System	17 Sep 2020 02:02:06
User entered 'No (N)'	System	17 Sep 2020 02:02:06

FDA-CBER-2022-1614-0192621

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-16T21:02:02', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'af4e6ec7-8191-4eb0-89c5-ce0d88b376b2'	System	17 Sep 2020 02:02:06
User entered '16 Sep 2020 21:02'	System	17 Sep 2020 02:02:06

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192623

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192624

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 4'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192625

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:58:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-17T21:11:45', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'ec635594-a682-4af7-8278-874147a396ea'	System	18 Sep 2020 02:11:59
User entered 'Yes (Y)'	System	18 Sep 2020 02:11:59

FDA-CBER-2022-1614-0192626

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:58:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-17T21:11:51', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'ec635594-a682-4af7-8278-874147a396ea'	System	18 Sep 2020 02:11:59
User entered '97.1'	System	18 Sep 2020 02:11:59

FDA-CBER-2022-1614-0192627

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:58:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-17T21:11:54', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'ec635594-a682-4af7-8278-874147a396ea'	System	18 Sep 2020 02:11:59
User entered 'No (N)'	System	18 Sep 2020 02:11:59

FDA-CBER-2022-1614-0192628

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-17T21:11:57', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'ec635594-a682-4af7-8278-874147a396ea'	System	18 Sep 2020 02:11:59
User entered '17 Sep 2020 21:11'	System	18 Sep 2020 02:11:59

FDA-CBER-2022-1614-0192629

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192630

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192631

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 5'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192632

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:58:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:18:30', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'fb628f43-0b9f-43ce-9787-cb232e8ce6c9'	System	19 Sep 2020 00:19:13
User entered 'Yes (Y)'	System	19 Sep 2020 00:19:13

FDA-CBER-2022-1614-0192633

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:58:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:18:38', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'fb628f43-0b9f-43ce-9787-cb232e8ce6c9'	System	19 Sep 2020 00:19:13
User entered '97.5'	System	19 Sep 2020 00:19:13

FDA-CBER-2022-1614-0192634

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:58:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:18:48', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'fb628f43-0b9f-43ce-9787-cb232e8ce6c9'	System	19 Sep 2020 00:19:13
User entered 'Yes (Y)'	System	19 Sep 2020 00:19:13

FDA-CBER-2022-1614-0192635

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:58:46
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 14:05:08
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant was contacted' (Site from System).	Jamie Thompson (b) (4) (b) (4)	22 Sep 2020 16:00:03
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	19 Sep 2020 00:19:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:19:01', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'fb628f43-0b9f-43ce-9787-cb232e8ce6c9'	System	19 Sep 2020 00:19:13
User entered '1'	System	19 Sep 2020 00:19:13

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:58:46
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:19:01', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'fb628f43-0b9f-43ce-9787-cb232e8ce6c9'	System	19 Sep 2020 00:19:13
User entered '0'	System	19 Sep 2020 00:19:13

FDA-CBER-2022-1614-0192637

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:19:10', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'fb628f43-0b9f-43ce-9787-cb232e8ce6c9'	System	19 Sep 2020 00:19:13
User entered '18 Sep 2020 19:19'	System	19 Sep 2020 00:19:13

FDA-CBER-2022-1614-0192638

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192639

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192640

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 6'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192641

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:58:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T02:30:37', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '8ba56a20-4a0b-4ac9-9ce2-23947f34e19d'	System	20 Sep 2020 07:30:52
User entered 'Yes (Y)'	System	20 Sep 2020 07:30:52

FDA-CBER-2022-1614-0192642

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:58:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T02:30:44', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '8ba56a20-4a0b-4ac9-9ce2-23947f34e19d'	System	20 Sep 2020 07:30:52
User entered '97.3'	System	20 Sep 2020 07:30:52

FDA-CBER-2022-1614-0192643

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:58:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T02:30:47', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '8ba56a20-4a0b-4ac9-9ce2-23947f34e19d'	System	20 Sep 2020 07:30:52
User entered 'No (N)'	System	20 Sep 2020 07:30:52

FDA-CBER-2022-1614-0192644

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T02:30:50', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '8ba56a20-4a0b-4ac9-9ce2-23947f34e19d'	System	20 Sep 2020 07:30:52
User entered '20 Sep 2020 02:30'	System	20 Sep 2020 07:30:52

FDA-CBER-2022-1614-0192645

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192646

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192647

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 7'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192648

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:58:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T22:47:41', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '539c03c2-46df-4ef4-897a-fd397b814b95'	System	21 Sep 2020 03:48:02
User entered 'Yes (Y)'	System	21 Sep 2020 03:48:02

FDA-CBER-2022-1614-0192649

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:58:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T22:47:52', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '539c03c2-46df-4ef4-897a-fd397b814b95'	System	21 Sep 2020 03:48:02
User entered '97.7'	System	21 Sep 2020 03:48:02

FDA-CBER-2022-1614-0192650

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:58:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T22:47:55', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '539c03c2-46df-4ef4-897a-fd397b814b95'	System	21 Sep 2020 03:48:02
User entered 'No (N)'	System	21 Sep 2020 03:48:02

FDA-CBER-2022-1614-0192651

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T22:47:58', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '539c03c2-46df-4ef4-897a-fd397b814b95'	System	21 Sep 2020 03:48:02
User entered '20 Sep 2020 22:47'	System	21 Sep 2020 03:48:02

FDA-CBER-2022-1614-0192652

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192653

US3042210
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192654

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192655

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T18:11:57', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '6b55d060-6ba8-4a2b-9ea5-f79371de1338'	System	14 Sep 2020 23:12:12
User entered 'None (1)'	System	14 Sep 2020 23:12:12

FDA-CBER-2022-1614-0192656

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T18:12:01', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '6b55d060-6ba8-4a2b-9ea5-f79371de1338'	System	14 Sep 2020 23:12:12
User entered 'No (N)'	System	14 Sep 2020 23:12:12

FDA-CBER-2022-1614-0192657

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T18:12:03', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '6b55d060-6ba8-4a2b-9ea5-f79371de1338'	System	14 Sep 2020 23:12:12
User entered 'No (N)'	System	14 Sep 2020 23:12:12

FDA-CBER-2022-1614-0192658

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T18:12:06', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '6b55d060-6ba8-4a2b-9ea5-f79371de1338'	System	14 Sep 2020 23:12:12
User entered 'None (1)'	System	14 Sep 2020 23:12:12

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T18:12:09', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '6b55d060-6ba8-4a2b-9ea5-f79371de1338'	System	14 Sep 2020 23:12:12
User entered '14 Sep 2020 18:12'	System	14 Sep 2020 23:12:12

FDA-CBER-2022-1614-0192660

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '14 Sep 2020 17:56'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192661

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '14 Sep 2020 20:26'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192662

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192663

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T21:39:09', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'e70f1f11-b56a-4deb-b9a1-a89c6c7f61d5'	System	15 Sep 2020 02:39:20
User entered 'None (1)'	System	15 Sep 2020 02:39:20

FDA-CBER-2022-1614-0192664

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T21:39:11', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'e70f1f11-b56a-4deb-b9a1-a89c6c7f61d5'	System	15 Sep 2020 02:39:20
User entered 'No (N)'	System	15 Sep 2020 02:39:20

FDA-CBER-2022-1614-0192665

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T21:39:13', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'e70f1f11-b56a-4deb-b9a1-a89c6c7f61d5'	System	15 Sep 2020 02:39:20
User entered 'No (N)'	System	15 Sep 2020 02:39:20

FDA-CBER-2022-1614-0192666

US3042210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T21:39:15', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'e70f1f11-b56a-4deb-b9a1-a89c6c7f61d5'	System	15 Sep 2020 02:39:20
User entered 'None (1)'	System	15 Sep 2020 02:39:20

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T21:39:18', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'e70f1f11-b56a-4deb-b9a1-a89c6c7f61d5'	System	15 Sep 2020 02:39:20
User entered '14 Sep 2020 21:39'	System	15 Sep 2020 02:39:20

FDA-CBER-2022-1614-0192668

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '14 Sep 2020 21:21'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192669

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192670

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 2'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192671

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:58:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-15T19:50:51', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '7c456702-41ab-4bbc-a506-61afad099610'	System	16 Sep 2020 00:51:11
User entered 'None (1)'	System	16 Sep 2020 00:51:11

FDA-CBER-2022-1614-0192672

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:58:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-15T19:50:56', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '7c456702-41ab-4bbc-a506-61afad099610'	System	16 Sep 2020 00:51:11
User entered 'No (N)'	System	16 Sep 2020 00:51:11

FDA-CBER-2022-1614-0192673

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:58:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-15T19:50:59', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '7c456702-41ab-4bbc-a506-61afad099610'	System	16 Sep 2020 00:51:11
User entered 'No (N)'	System	16 Sep 2020 00:51:11

FDA-CBER-2022-1614-0192674

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:58:46
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-15T19:51:01', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '7c456702-41ab-4bbc-a506-61afad099610'	System	16 Sep 2020 00:51:11
User entered 'None (1)'	System	16 Sep 2020 00:51:11

FDA-CBER-2022-1614-0192675

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-15T19:51:07', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '7c456702-41ab-4bbc-a506-61afad099610'	System	16 Sep 2020 00:51:11
User entered '15 Sep 2020 19:51'	System	16 Sep 2020 00:51:11

FDA-CBER-2022-1614-0192676

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192677

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192678

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 3'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192679

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:58:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-16T21:02:06', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '3e26606f-e771-4f03-b5a0-0e8e4c9f828a'	System	17 Sep 2020 02:02:22
User entered 'None (1)'	System	17 Sep 2020 02:02:22

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:58:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-16T21:02:08', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '3e26606f-e771-4f03-b5a0-0e8e4c9f828a'	System	17 Sep 2020 02:02:22
User entered 'No (N)'	System	17 Sep 2020 02:02:22

FDA-CBER-2022-1614-0192681

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:58:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-16T21:02:11', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '3e26606f-e771-4f03-b5a0-0e8e4c9f828a'	System	17 Sep 2020 02:02:22
User entered 'No (N)'	System	17 Sep 2020 02:02:22

FDA-CBER-2022-1614-0192682

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:58:46
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-16T21:02:13', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '3e26606f-e771-4f03-b5a0-0e8e4c9f828a'	System	17 Sep 2020 02:02:22
User entered 'None (1)'	System	17 Sep 2020 02:02:22

FDA-CBER-2022-1614-0192683

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-16T21:02:18', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '3e26606f-e771-4f03-b5a0-0e8e4c9f828a'	System	17 Sep 2020 02:02:22
User entered '16 Sep 2020 21:02'	System	17 Sep 2020 02:02:22

FDA-CBER-2022-1614-0192684

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192685

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192686

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 4'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192687

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-17T21:12:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '36f20f15-509c-4217-8d6f-6b796d766a75'	System	18 Sep 2020 02:12:16
User entered 'None (1)'	System	18 Sep 2020 02:12:16

FDA-CBER-2022-1614-0192688

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-17T21:12:03', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '36f20f15-509c-4217-8d6f-6b796d766a75'	System	18 Sep 2020 02:12:16
User entered 'No (N)'	System	18 Sep 2020 02:12:16

FDA-CBER-2022-1614-0192689

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-17T21:12:05', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '36f20f15-509c-4217-8d6f-6b796d766a75'	System	18 Sep 2020 02:12:16
User entered 'No (N)'	System	18 Sep 2020 02:12:16

FDA-CBER-2022-1614-0192690

US3042210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-17T21:12:09', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '36f20f15-509c-4217-8d6f-6b796d766a75'	System	18 Sep 2020 02:12:16
User entered 'None (1)'	System	18 Sep 2020 02:12:16

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-17T21:12:11', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '36f20f15-509c-4217-8d6f-6b796d766a75'	System	18 Sep 2020 02:12:16
User entered '17 Sep 2020 21:12'	System	18 Sep 2020 02:12:16

FDA-CBER-2022-1614-0192692

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192693

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192694

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 5'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192695

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:58:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:19:13', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '069dbf5e-2b59-4ff2-ae09-c8dbc730446a'	System	19 Sep 2020 00:19:30
User entered 'None (1)'	System	19 Sep 2020 00:19:30

FDA-CBER-2022-1614-0192696

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:58:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:19:17', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '069dbf5e-2b59-4ff2-ae09-c8dbc730446a'	System	19 Sep 2020 00:19:30
User entered 'No (N)'	System	19 Sep 2020 00:19:30

FDA-CBER-2022-1614-0192697

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:58:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:19:19', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '069dbf5e-2b59-4ff2-ae09-c8dbc730446a'	System	19 Sep 2020 00:19:30
User entered 'No (N)'	System	19 Sep 2020 00:19:30

FDA-CBER-2022-1614-0192698

US3042210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:19:22', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '069dbf5e-2b59-4ff2-ae09-c8dbc730446a'	System	19 Sep 2020 00:19:30
User entered 'None (1)'	System	19 Sep 2020 00:19:30

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:19:27', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '069dbf5e-2b59-4ff2-ae09-c8dbc730446a'	System	19 Sep 2020 00:19:30
User entered '18 Sep 2020 19:19'	System	19 Sep 2020 00:19:30

FDA-CBER-2022-1614-0192700

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192701

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192702

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 6'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192703

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:58:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T02:30:54', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'aea46884-c3af-45a4-b092-e034168375e3'	System	20 Sep 2020 07:31:10
User entered 'None (1)'	System	20 Sep 2020 07:31:10

FDA-CBER-2022-1614-0192704

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:58:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T02:30:56', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'aea46884-c3af-45a4-b092-e034168375e3'	System	20 Sep 2020 07:31:10
User entered 'No (N)'	System	20 Sep 2020 07:31:10

FDA-CBER-2022-1614-0192705

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:58:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T02:30:59', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'aea46884-c3af-45a4-b092-e034168375e3'	System	20 Sep 2020 07:31:10
User entered 'No (N)'	System	20 Sep 2020 07:31:10

FDA-CBER-2022-1614-0192706

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:58:46
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T02:31:01', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'aea46884-c3af-45a4-b092-e034168375e3'	System	20 Sep 2020 07:31:10
User entered 'None (1)'	System	20 Sep 2020 07:31:10

FDA-CBER-2022-1614-0192707

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T02:31:06', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'aea46884-c3af-45a4-b092-e034168375e3'	System	20 Sep 2020 07:31:10
User entered '20 Sep 2020 02:31'	System	20 Sep 2020 07:31:10

FDA-CBER-2022-1614-0192708

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192709

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192710

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 7'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192711

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:58:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T22:48:02', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '7450f5a2-08fc-4f33-ae5a-a9c324bca776'	System	21 Sep 2020 03:48:15
User entered 'None (1)'	System	21 Sep 2020 03:48:15

FDA-CBER-2022-1614-0192712

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:58:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T22:48:05', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '7450f5a2-08fc-4f33-ae5a-a9c324bca776'	System	21 Sep 2020 03:48:15
User entered 'No (N)'	System	21 Sep 2020 03:48:15

FDA-CBER-2022-1614-0192713

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:58:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T22:48:07', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '7450f5a2-08fc-4f33-ae5a-a9c324bca776'	System	21 Sep 2020 03:48:15
User entered 'No (N)'	System	21 Sep 2020 03:48:15

FDA-CBER-2022-1614-0192714

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:58:46
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T22:48:09', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '7450f5a2-08fc-4f33-ae5a-a9c324bca776'	System	21 Sep 2020 03:48:15
User entered 'None (1)'	System	21 Sep 2020 03:48:15

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:58:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T22:48:13', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '7450f5a2-08fc-4f33-ae5a-a9c324bca776'	System	21 Sep 2020 03:48:15
User entered '20 Sep 2020 22:48'	System	21 Sep 2020 03:48:15

FDA-CBER-2022-1614-0192716

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192717

US3042210
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192718

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192719

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T18:12:14', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'd8d6bb54-bc16-429b-8cb1-a9b64ddda965'	System	14 Sep 2020 23:12:44
User entered 'None (0)'	System	14 Sep 2020 23:12:44

FDA-CBER-2022-1614-0192720

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T18:12:16', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'd8d6bb54-bc16-429b-8cb1-a9b64ddda965'	System	14 Sep 2020 23:12:44
User entered 'None (0)'	System	14 Sep 2020 23:12:44

FDA-CBER-2022-1614-0192721

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T18:12:18', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'd8d6bb54-bc16-429b-8cb1-a9b64ddda965'	System	14 Sep 2020 23:12:44
User entered 'None (0)'	System	14 Sep 2020 23:12:44

FDA-CBER-2022-1614-0192722

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T18:12:21', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'd8d6bb54-bc16-429b-8cb1-a9b64ddda965'	System	14 Sep 2020 23:12:44
User entered 'None (0)'	System	14 Sep 2020 23:12:44

FDA-CBER-2022-1614-0192723

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T18:12:23', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'd8d6bb54-bc16-429b-8cb1-a9b64ddda965'	System	14 Sep 2020 23:12:44
User entered 'None (0)'	System	14 Sep 2020 23:12:44

FDA-CBER-2022-1614-0192724

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T18:12:31', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'd8d6bb54-bc16-429b-8cb1-a9b64ddda965'	System	14 Sep 2020 23:12:44
User entered 'None (0)'	System	14 Sep 2020 23:12:44

FDA-CBER-2022-1614-0192725

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T18:12:36', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'd8d6bb54-bc16-429b-8cb1-a9b64ddda965'	System	14 Sep 2020 23:12:44
User entered 'No (N)'	System	14 Sep 2020 23:12:44

FDA-CBER-2022-1614-0192726

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T18:12:40', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'd8d6bb54-bc16-429b-8cb1-a9b64ddda965'	System	14 Sep 2020 23:12:44
User entered '14 Sep 2020 18:12'	System	14 Sep 2020 23:12:44

FDA-CBER-2022-1614-0192727

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '14 Sep 2020 17:56'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192728

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '14 Sep 2020 20:26'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192729

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192730

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T21:39:26', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '63148201-9556-4e1c-affc-27c070bfabd3'	System	15 Sep 2020 02:39:45
User entered 'No interference with activity (1)'	System	15 Sep 2020 02:39:45

FDA-CBER-2022-1614-0192731

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T21:39:30', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '63148201-9556-4e1c-affc-27c070bfabd3'	System	15 Sep 2020 02:39:45
User entered 'None (0)'	System	15 Sep 2020 02:39:45

FDA-CBER-2022-1614-0192732

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T21:39:31', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '63148201-9556-4e1c-affc-27c070bfabd3'	System	15 Sep 2020 02:39:45
User entered 'None (0)'	System	15 Sep 2020 02:39:45

FDA-CBER-2022-1614-0192733

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T21:39:33', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '63148201-9556-4e1c-affc-27c070bfabd3'	System	15 Sep 2020 02:39:45
User entered 'None (0)'	System	15 Sep 2020 02:39:45

FDA-CBER-2022-1614-0192734

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T21:39:35', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '63148201-9556-4e1c-affc-27c070bfabd3'	System	15 Sep 2020 02:39:45
User entered 'None (0)'	System	15 Sep 2020 02:39:45

FDA-CBER-2022-1614-0192735

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T21:39:37', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '63148201-9556-4e1c-affc-27c070bfabd3'	System	15 Sep 2020 02:39:45
User entered 'None (0)'	System	15 Sep 2020 02:39:45

FDA-CBER-2022-1614-0192736

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T21:39:39', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '63148201-9556-4e1c-affc-27c070bfabd3'	System	15 Sep 2020 02:39:45
User entered 'No (N)'	System	15 Sep 2020 02:39:45

FDA-CBER-2022-1614-0192737

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-14T21:39:41', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '63148201-9556-4e1c-affc-27c070bfabd3'	System	15 Sep 2020 02:39:45
User entered '14 Sep 2020 21:39'	System	15 Sep 2020 02:39:45

FDA-CBER-2022-1614-0192738

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '14 Sep 2020 21:21'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192739

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192740

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 2'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192741

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-15T19:51:12', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'c13ab7a0-5fb9-4f4a-98da-62b490e30023'	System	16 Sep 2020 00:51:32
User entered 'None (0)'	System	16 Sep 2020 00:51:32

FDA-CBER-2022-1614-0192742

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-15T19:51:13', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'c13ab7a0-5fb9-4f4a-98da-62b490e30023'	System	16 Sep 2020 00:51:32
User entered 'None (0)'	System	16 Sep 2020 00:51:32

FDA-CBER-2022-1614-0192743

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-15T19:51:16', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'c13ab7a0-5fb9-4f4a-98da-62b490e30023'	System	16 Sep 2020 00:51:32
User entered 'None (0)'	System	16 Sep 2020 00:51:32

FDA-CBER-2022-1614-0192744

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-15T19:51:18', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'c13ab7a0-5fb9-4f4a-98da-62b490e30023'	System	16 Sep 2020 00:51:32
User entered 'None (0)'	System	16 Sep 2020 00:51:32

FDA-CBER-2022-1614-0192745

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-15T19:51:19', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'c13ab7a0-5fb9-4f4a-98da-62b490e30023'	System	16 Sep 2020 00:51:32
User entered 'None (0)'	System	16 Sep 2020 00:51:32

FDA-CBER-2022-1614-0192746

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-15T19:51:21', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'c13ab7a0-5fb9-4f4a-98da-62b490e30023'	System	16 Sep 2020 00:51:32
User entered 'None (0)'	System	16 Sep 2020 00:51:32

FDA-CBER-2022-1614-0192747

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-15T19:51:24', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'c13ab7a0-5fb9-4f4a-98da-62b490e30023'	System	16 Sep 2020 00:51:32
User entered 'No (N)'	System	16 Sep 2020 00:51:32

FDA-CBER-2022-1614-0192748

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-15T19:51:28', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'c13ab7a0-5fb9-4f4a-98da-62b490e30023'	System	16 Sep 2020 00:51:32
User entered '15 Sep 2020 19:51'	System	16 Sep 2020 00:51:32

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192750

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192751

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 3'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192752

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-16T21:02:22', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'c8ebd6bd-738b-40d5-b499-181380baf063'	System	17 Sep 2020 02:02:43
User entered 'None (0)'	System	17 Sep 2020 02:02:43

FDA-CBER-2022-1614-0192753

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-16T21:02:24', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'c8ebd6bd-738b-40d5-b499-181380baf063'	System	17 Sep 2020 02:02:43
User entered 'None (0)'	System	17 Sep 2020 02:02:43

FDA-CBER-2022-1614-0192754

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-16T21:02:26', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'c8ebd6bd-738b-40d5-b499-181380baf063'	System	17 Sep 2020 02:02:43
User entered 'None (0)'	System	17 Sep 2020 02:02:43

FDA-CBER-2022-1614-0192755

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-16T21:02:28', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'c8ebd6bd-738b-40d5-b499-181380baf063'	System	17 Sep 2020 02:02:43
User entered 'None (0)'	System	17 Sep 2020 02:02:43

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-16T21:02:30', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'c8ebd6bd-738b-40d5-b499-181380baf063'	System	17 Sep 2020 02:02:43
User entered 'None (0)'	System	17 Sep 2020 02:02:43

FDA-CBER-2022-1614-0192757

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-16T21:02:33', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'c8ebd6bd-738b-40d5-b499-181380baf063'	System	17 Sep 2020 02:02:43
User entered 'None (0)'	System	17 Sep 2020 02:02:43

FDA-CBER-2022-1614-0192758

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-16T21:02:36', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'c8ebd6bd-738b-40d5-b499-181380baf063'	System	17 Sep 2020 02:02:43
User entered 'No (N)'	System	17 Sep 2020 02:02:43

FDA-CBER-2022-1614-0192759

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-16T21:02:38', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'c8ebd6bd-738b-40d5-b499-181380baf063'	System	17 Sep 2020 02:02:43
User entered '16 Sep 2020 21:02'	System	17 Sep 2020 02:02:43

FDA-CBER-2022-1614-0192760

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192761

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192762

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 4'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192763

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-17T21:12:16', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'bad67846-3b6c-49f0-ac11-9e6f45d170c5'	System	18 Sep 2020 02:12:38
User entered 'No interference with activity (1)'	System	18 Sep 2020 02:12:38

FDA-CBER-2022-1614-0192764

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-17T21:12:21', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'bad67846-3b6c-49f0-ac11-9e6f45d170c5'	System	18 Sep 2020 02:12:38
User entered 'No interference with activity (1)'	System	18 Sep 2020 02:12:38

FDA-CBER-2022-1614-0192765

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-17T21:12:24', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'bad67846-3b6c-49f0-ac11-9e6f45d170c5'	System	18 Sep 2020 02:12:38
User entered 'No interference with activity (1)'	System	18 Sep 2020 02:12:38

FDA-CBER-2022-1614-0192766

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-17T21:12:27', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'bad67846-3b6c-49f0-ac11-9e6f45d170c5'	System	18 Sep 2020 02:12:38
User entered 'None (0)'	System	18 Sep 2020 02:12:38

FDA-CBER-2022-1614-0192767

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-17T21:12:29', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'bad67846-3b6c-49f0-ac11-9e6f45d170c5'	System	18 Sep 2020 02:12:38
User entered 'None (0)'	System	18 Sep 2020 02:12:38

FDA-CBER-2022-1614-0192768

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-17T21:12:31', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'bad67846-3b6c-49f0-ac11-9e6f45d170c5'	System	18 Sep 2020 02:12:38
User entered 'None (0)'	System	18 Sep 2020 02:12:38

FDA-CBER-2022-1614-0192769

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-17T21:12:33', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'bad67846-3b6c-49f0-ac11-9e6f45d170c5'	System	18 Sep 2020 02:12:38
User entered 'No (N)'	System	18 Sep 2020 02:12:38

FDA-CBER-2022-1614-0192770

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-17T21:12:35', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'bad67846-3b6c-49f0-ac11-9e6f45d170c5'	System	18 Sep 2020 02:12:38
User entered '17 Sep 2020 21:12'	System	18 Sep 2020 02:12:38

FDA-CBER-2022-1614-0192771

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192772

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192773

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 5'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192774

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:20:12', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '37879b16-fea5-4942-87ad-7291cf16a3b8'	System	19 Sep 2020 00:21:10
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	19 Sep 2020 00:21:10

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:20:18', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '37879b16-fea5-4942-87ad-7291cf16a3b8'	System	19 Sep 2020 00:21:10
User entered 'Some interference with activity (2)'	System	19 Sep 2020 00:21:10

FDA-CBER-2022-1614-0192776

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:20:38', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '37879b16-fea5-4942-87ad-7291cf16a3b8'	System	19 Sep 2020 00:21:10
User entered 'No interference with activity (1)'	System	19 Sep 2020 00:21:10

FDA-CBER-2022-1614-0192777

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:20:42', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '37879b16-fea5-4942-87ad-7291cf16a3b8'	System	19 Sep 2020 00:21:10
User entered 'None (0)'	System	19 Sep 2020 00:21:10

FDA-CBER-2022-1614-0192778

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:20:47', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '37879b16-fea5-4942-87ad-7291cf16a3b8'	System	19 Sep 2020 00:21:10
User entered 'None (0)'	System	19 Sep 2020 00:21:10

FDA-CBER-2022-1614-0192779

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:20:50', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '37879b16-fea5-4942-87ad-7291cf16a3b8'	System	19 Sep 2020 00:21:10
User entered 'None (0)'	System	19 Sep 2020 00:21:10

FDA-CBER-2022-1614-0192780

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:20:53', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '37879b16-fea5-4942-87ad-7291cf16a3b8'	System	19 Sep 2020 00:21:10
User entered 'No (N)'	System	19 Sep 2020 00:21:10

FDA-CBER-2022-1614-0192781

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-18T19:21:06', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '37879b16-fea5-4942-87ad-7291cf16a3b8'	System	19 Sep 2020 00:21:10
User entered '18 Sep 2020 19:21'	System	19 Sep 2020 00:21:10

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192783

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192784

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 6'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192785

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T02:31:11', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '09e5af0b-c19b-4a36-a965-45a1736754f5'	System	20 Sep 2020 07:31:36
User entered 'No interference with activity (1)'	System	20 Sep 2020 07:31:36

FDA-CBER-2022-1614-0192786

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T02:31:15', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '09e5af0b-c19b-4a36-a965-45a1736754f5'	System	20 Sep 2020 07:31:36
User entered 'No interference with activity (1)'	System	20 Sep 2020 07:31:36

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T02:31:19', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '09e5af0b-c19b-4a36-a965-45a1736754f5'	System	20 Sep 2020 07:31:36
User entered 'None (0)'	System	20 Sep 2020 07:31:36

FDA-CBER-2022-1614-0192788

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T02:31:21', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '09e5af0b-c19b-4a36-a965-45a1736754f5'	System	20 Sep 2020 07:31:36
User entered 'None (0)'	System	20 Sep 2020 07:31:36

FDA-CBER-2022-1614-0192789

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T02:31:24', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '09e5af0b-c19b-4a36-a965-45a1736754f5'	System	20 Sep 2020 07:31:36
User entered 'None (0)'	System	20 Sep 2020 07:31:36

FDA-CBER-2022-1614-0192790

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T02:31:26', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '09e5af0b-c19b-4a36-a965-45a1736754f5'	System	20 Sep 2020 07:31:36
User entered 'None (0)'	System	20 Sep 2020 07:31:36

FDA-CBER-2022-1614-0192791

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T02:31:29', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '09e5af0b-c19b-4a36-a965-45a1736754f5'	System	20 Sep 2020 07:31:36
User entered 'No (N)'	System	20 Sep 2020 07:31:36

FDA-CBER-2022-1614-0192792

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T02:31:33', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '09e5af0b-c19b-4a36-a965-45a1736754f5'	System	20 Sep 2020 07:31:36
User entered '20 Sep 2020 02:31'	System	20 Sep 2020 07:31:36

FDA-CBER-2022-1614-0192793

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192794

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192795

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	14 Sep 2020 22:39:36
User entered 'Day 7'	System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192796

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T22:48:17', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '48416abb-de6c-44d7-a2e1-8515c1b50897'	System	21 Sep 2020 03:48:39
User entered 'None (0)'	System	21 Sep 2020 03:48:39

FDA-CBER-2022-1614-0192797

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T22:48:20', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '48416abb-de6c-44d7-a2e1-8515c1b50897'	System	21 Sep 2020 03:48:39
User entered 'None (0)'	System	21 Sep 2020 03:48:39

FDA-CBER-2022-1614-0192798

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T22:48:22', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '48416abb-de6c-44d7-a2e1-8515c1b50897'	System	21 Sep 2020 03:48:39
User entered 'None (0)'	System	21 Sep 2020 03:48:39

FDA-CBER-2022-1614-0192799

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T22:48:24', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '48416abb-de6c-44d7-a2e1-8515c1b50897'	System	21 Sep 2020 03:48:39
User entered 'None (0)'	System	21 Sep 2020 03:48:39

FDA-CBER-2022-1614-0192800

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T22:48:26', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '48416abb-de6c-44d7-a2e1-8515c1b50897'	System	21 Sep 2020 03:48:39
User entered 'None (0)'	System	21 Sep 2020 03:48:39

FDA-CBER-2022-1614-0192801

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T22:48:28', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '48416abb-de6c-44d7-a2e1-8515c1b50897'	System	21 Sep 2020 03:48:39
User entered 'None (0)'	System	21 Sep 2020 03:48:39

FDA-CBER-2022-1614-0192802

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T22:48:31', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '48416abb-de6c-44d7-a2e1-8515c1b50897'	System	21 Sep 2020 03:48:39
User entered 'No (N)'	System	21 Sep 2020 03:48:39

FDA-CBER-2022-1614-0192803

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-09-20T22:48:36', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '48416abb-de6c-44d7-a2e1-8515c1b50897'	System	21 Sep 2020 03:48:39
User entered '20 Sep 2020 22:48'	System	21 Sep 2020 03:48:39

FDA-CBER-2022-1614-0192804

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192805

US3042210
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:58:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:28
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 22:39:36

FDA-CBER-2022-1614-0192806

US3042210
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 07:04:44
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:41:03
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	28 Sep 2020 17:52:25

FDA-CBER-2022-1614-0192807

US3042210
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 07:04:44
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:41:03
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 08:51:18
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'SUBJECT WAS LEFT MESSAGES 21SEP2020 AND 23SEP2020' (Site from System).	Rylea Gulick (b) (4) (b) (4)	28 Sep 2020 17:52:56
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Sep 2020 17:52:25
User entered '25 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	28 Sep 2020 17:52:25

US3042210
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 07:04:44
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:41:03
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4) (b) (4)	28 Sep 2020 17:52:25

FDA-CBER-2022-1614-0192809

US3042210
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 07:04:44
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:41:03
User entered empty.	Rylea Gulick (b) (4) (b) (4)	28 Sep 2020 17:52:25

FDA-CBER-2022-1614-0192810

US3042210
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 07:04:44
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:41:13
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	28 Sep 2020 17:53:00

FDA-CBER-2022-1614-0192811

US3042210
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:44
User entered '1'	(b) (4), (b) (6) System	28 Sep 2020 17:53:00

FDA-CBER-2022-1614-0192812

US3042210
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 13:53:19
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:43:33
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:07:50

US3042210
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 13:53:19
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:43:33
User entered '28 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:07:50

US3042210
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 13:53:19
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:43:33
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:07:50

US3042210
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 13:53:19
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:43:33
User entered empty.	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:07:50

FDA-CBER-2022-1614-0192816

US3042210
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 13:53:19
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:43:40
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:07:53

US3042210
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:19
User entered '1'	(b) (4), (b) (6) System	12 Oct 2020 19:07:53

FDA-CBER-2022-1614-0192818

US3042210
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:56:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:43:53
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:08

US3042210
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:56:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:43:53
User entered '05 Oct 2020'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:08

US3042210
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:56:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:43:53
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:08

US3042210
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:56:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:43:53
User entered empty.	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:08

FDA-CBER-2022-1614-0192822

US3042210
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:56:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:44:02
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:10

US3042210
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:56:28
User entered '1'	System	12 Oct 2020 19:08:10

FDA-CBER-2022-1614-0192824

US3042210
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:44:46
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:28

US3042210
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:44:46
User entered '12 Oct 2020'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:28

FDA-CBER-2022-1614-0192826

US3042210
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:44:46
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:28

US3042210
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User entered 'VISIT3'	System	12 Oct 2020 19:08:28

FDA-CBER-2022-1614-0192828

US3042210
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:45:26
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:45

US3042210
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:45:26
User entered '12 Oct 2020'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:45

FDA-CBER-2022-1614-0192830

US3042210
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:45:26
User entered '13:01'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:45

FDA-CBER-2022-1614-0192831

US3042210
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User entered '12 Oct 2020 13:01'	System	12 Oct 2020 19:08:45

FDA-CBER-2022-1614-0192832

US3042210
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:45:26
User entered '36.4' C	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:45

US3042210
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:45:26
User entered 'Oral (Oral)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:45

US3042210
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:45:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:45

FDA-CBER-2022-1614-0192835

US3042210
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:45:26
User entered '63'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:45

FDA-CBER-2022-1614-0192836

US3042210
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:56
User entered 'bpm'	(b) (4), (b) (6) System	12 Oct 2020 19:08:45

FDA-CBER-2022-1614-0192837

US3042210
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:45:26
User entered '12'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:45

FDA-CBER-2022-1614-0192838

US3042210
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:56
User entered 'breaths/min'	(b) (4), (b) (6) System	12 Oct 2020 19:08:45

FDA-CBER-2022-1614-0192839

US3042210
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:45:26
User entered '136'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:45

FDA-CBER-2022-1614-0192840

US3042210
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User entered 'mmHg'	System	12 Oct 2020 19:08:45

FDA-CBER-2022-1614-0192841

US3042210
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:45:26
User entered '86'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:45

US3042210
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User entered 'mmHg'	System	12 Oct 2020 19:08:45

FDA-CBER-2022-1614-0192843

US3042210
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56

FDA-CBER-2022-1614-0192844

US3042210
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56

FDA-CBER-2022-1614-0192845

US3042210
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:58:46
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:45:40
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:51

FDA-CBER-2022-1614-0192846

US3042210
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:58:46
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:45:40
User entered '12 Oct 2020'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:51

FDA-CBER-2022-1614-0192847

US3042210
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:45:51
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:59

US3042210
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:45:51
User entered '12 Oct 2020'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:59

FDA-CBER-2022-1614-0192849

US3042210
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:45:51
User entered '13:10'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:08:59

US3042210
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User entered '12 Oct 2020 13:10'	System	12 Oct 2020 19:08:59

FDA-CBER-2022-1614-0192851

US3042210
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:45:58
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 19:09:01

US3042210
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:56
User entered '1'	System	12 Oct 2020 19:09:01

FDA-CBER-2022-1614-0192853

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 64'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192854

US3042210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-10-19T14:36:02', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'ccdbff36-c31d-4184-907d-e0d988083557'	System	19 Oct 2020 19:36:24
User entered 'No (N)'	System	19 Oct 2020 19:36:24

US3042210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

Have you been exposed to someone with 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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-10-19T14:36:13', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'ccdbff36-c31d-4184-907d-e0d988083557'	System	19 Oct 2020 19:36:24
User entered 'No (N)'	System	19 Oct 2020 19:36:24

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-10-19T14:36:20', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'ccdbff36-c31d-4184-907d-e0d988083557'	System	19 Oct 2020 19:36:24
User entered '19 Oct 2020 14:36:20'	System	19 Oct 2020 19:36:24

FDA-CBER-2022-1614-0192857

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 15:21:08

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192859

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 71'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192860

US3042210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-10-25T21:34:56', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'ed45ce0d-837b-4bc7-8cf0-a50dea8837de'	System	26 Oct 2020 02:35:12
User entered 'No (N)'	System	26 Oct 2020 02:35:12

US3042210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

Have you been exposed to someone with 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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-10-25T21:35:04', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'ed45ce0d-837b-4bc7-8cf0-a50dea8837de'	System	26 Oct 2020 02:35:12
User entered 'No (N)'	System	26 Oct 2020 02:35:12

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-10-25T21:35:10', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'ed45ce0d-837b-4bc7-8cf0-a50dea8837de'	System	26 Oct 2020 02:35:12
User entered '25 Oct 2020 21:35:10'	System	26 Oct 2020 02:35:12

FDA-CBER-2022-1614-0192863

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192864

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192865

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 78'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192866

US3042210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-11-01T22:13:06', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '1aab01b2-badc-4521-8f9b-c430834f92d1'	System	02 Nov 2020 04:13:16
User entered 'No (N)'	System	02 Nov 2020 04:13:16

US3042210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

Have you been exposed to someone with 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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-11-01T22:13:09', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '1aab01b2-badc-4521-8f9b-c430834f92d1'	System	02 Nov 2020 04:13:16
User entered 'No (N)'	System	02 Nov 2020 04:13:16

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-11-01T22:13:12', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '1aab01b2-badc-4521-8f9b-c430834f92d1'	System	02 Nov 2020 04:13:16
User entered '01 Nov 2020 22:13:12'	System	02 Nov 2020 04:13:16

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192870

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192871

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered 'Day 92'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192872

US3042210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-11-17T20:17:40', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '306b871e-accf-45b7-a2d1-b39bc9443610'	System	18 Nov 2020 02:17:52
User entered 'No (N)'	System	18 Nov 2020 02:17:52

US3042210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

Have you been exposed to someone with 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) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-11-17T20:17:44', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '306b871e-accf-45b7-a2d1-b39bc9443610'	System	18 Nov 2020 02:17:52
User entered 'No (N)'	System	18 Nov 2020 02:17:52

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-11-17T20:17:48', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '306b871e-accf-45b7-a2d1-b39bc9443610'	System	18 Nov 2020 02:17:52
User entered '17 Nov 2020 20:17:48'	System	18 Nov 2020 02:17:52

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192876

US3042210
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:53:28
Data entry locked.	System	17 Aug 2020 15:21:08
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 15:21:08

FDA-CBER-2022-1614-0192877

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192878

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

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 (f5f55411d9299a2e)', Time: '2020-11-22T16:51:07', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '2803e379-6292-422a-8dc2-1c20f5650bc5'	System	22 Nov 2020 22:51:18
User entered 'No (N)'	System	22 Nov 2020 22:51:18

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

Have you been exposed to someone with 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 (f5f55411d9299a2e)', Time: '2020-11-22T16:51:10', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '2803e379-6292-422a-8dc2-1c20f5650bc5'	System	22 Nov 2020 22:51:18
User entered 'No (N)'	System	22 Nov 2020 22:51:18

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-11-22T16:51:13', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '2803e379-6292-422a-8dc2-1c20f5650bc5'	System	22 Nov 2020 22:51:18
User entered '22 Nov 2020 16:51:13'	System	22 Nov 2020 22:51:18

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192882

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192883

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:06:40

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

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 (f5f55411d9299a2e)', Time: '2020-11-29T12:46:04', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '69a01abf-5843-44c9-b298-b313ca218a5c'	System	29 Nov 2020 18:46:16
User entered 'No (N)'	System	29 Nov 2020 18:46:16

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

Have you been exposed to someone with 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 (f5f55411d9299a2e)', Time: '2020-11-29T12:46:07', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '69a01abf-5843-44c9-b298-b313ca218a5c'	System	29 Nov 2020 18:46:16
User entered 'No (N)'	System	29 Nov 2020 18:46:16

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-11-29T12:46:10', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '69a01abf-5843-44c9-b298-b313ca218a5c'	System	29 Nov 2020 18:46:16
User entered '29 Nov 2020 12:46:10'	System	29 Nov 2020 18:46:16

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192888

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192889

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192891

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192892

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192894

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192895

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192896

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

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 (f5f55411d9299a2e)', Time: '2020-12-17T20:52:46', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '2b18890c-e8e6-424a-b437-db1b40ab4205'	System	18 Dec 2020 02:52:55
User entered 'No (N)'	System	18 Dec 2020 02:52:55

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

Have you been exposed to someone with 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 (f5f55411d9299a2e)', Time: '2020-12-17T20:52:49', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '2b18890c-e8e6-424a-b437-db1b40ab4205'	System	18 Dec 2020 02:52:55
User entered 'No (N)'	System	18 Dec 2020 02:52:55

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2020-12-17T20:52:52', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '2b18890c-e8e6-424a-b437-db1b40ab4205'	System	18 Dec 2020 02:52:55
User entered '17 Dec 2020 20:52:52'	System	18 Dec 2020 02:52:55

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192901

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192904

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192906

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192907

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:06:40

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

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 (f5f55411d9299a2e)', Time: '2021-01-08T19:31:28', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '8b8f5046-6464-4ecd-8e14-07925abf7ecd'	System	09 Jan 2021 01:31:42
User entered 'No (N)'	System	09 Jan 2021 01:31:42

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

Have you been exposed to someone with 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 (f5f55411d9299a2e)', Time: '2021-01-08T19:31:33', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '8b8f5046-6464-4ecd-8e14-07925abf7ecd'	System	09 Jan 2021 01:31:42
User entered 'No (N)'	System	09 Jan 2021 01:31:42

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2021-01-08T19:31:37', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '8b8f5046-6464-4ecd-8e14-07925abf7ecd'	System	09 Jan 2021 01:31:42
User entered '08 Jan 2021 19:31:37'	System	09 Jan 2021 01:31:42

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192912

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192913

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192916

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192919

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192920

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

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 (f5f55411d9299a2e)', Time: '2021-01-28T16:23:51', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'e4bf81a5-8bdd-489f-877d-c2549ccbd5fc'	System	28 Jan 2021 22:24:04
User entered 'No (N)'	System	28 Jan 2021 22:24:04

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

Have you been exposed to someone with 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 (f5f55411d9299a2e)', Time: '2021-01-28T16:23:55', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'e4bf81a5-8bdd-489f-877d-c2549ccbd5fc'	System	28 Jan 2021 22:24:04
User entered 'No (N)'	System	28 Jan 2021 22:24:04

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2021-01-28T16:23:59', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'e4bf81a5-8bdd-489f-877d-c2549ccbd5fc'	System	28 Jan 2021 22:24:04
User entered '28 Jan 2021 16:23:59'	System	28 Jan 2021 22:24:04

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192924

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192925

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192926

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

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 (f5f55411d9299a2e)', Time: '2021-02-03T20:03:04', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '22142a75-842d-45c1-95ac-8936c07da6c6'	System	04 Feb 2021 02:08:54
User entered 'No (N)'	System	04 Feb 2021 02:08:54

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

Have you been exposed to someone with 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 (f5f55411d9299a2e)', Time: '2021-02-03T20:03:05', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '22142a75-842d-45c1-95ac-8936c07da6c6'	System	04 Feb 2021 02:08:54
User entered 'No (N)'	System	04 Feb 2021 02:08:54

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2021-02-03T20:03:10', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '22142a75-842d-45c1-95ac-8936c07da6c6'	System	04 Feb 2021 02:08:54
User entered '03 Feb 2021 20:03:10'	System	04 Feb 2021 02:08:54

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192930

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192931

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 09:06:40

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

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 (f5f55411d9299a2e)', Time: '2021-02-12T13:24:15', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'f0f9bbed-ba0a-4993-bb28-80fbc6203d1d'	System	12 Feb 2021 19:24:42
User entered 'No (N)'	System	12 Feb 2021 19:24:42

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

Have you been exposed to someone with 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 (f5f55411d9299a2e)', Time: '2021-02-12T13:24:31', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'f0f9bbed-ba0a-4993-bb28-80fbc6203d1d'	System	12 Feb 2021 19:24:42
User entered 'No (N)'	System	12 Feb 2021 19:24:42

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2021-02-12T13:24:38', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'f0f9bbed-ba0a-4993-bb28-80fbc6203d1d'	System	12 Feb 2021 19:24:42
User entered '12 Feb 2021 13:24:38'	System	12 Feb 2021 19:24:42

FDA-CBER-2022-1614-0192935

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192936

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192937

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 09:06:40

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

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 (f5f55411d9299a2e)', Time: '2021-02-18T14:43:19', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '61c833d6-8846-4cf8-bcf5-ccee74900cad'	System	18 Feb 2021 20:43:33
User entered 'No (N)'	System	18 Feb 2021 20:43:33

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

Have you been exposed to someone with 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 (f5f55411d9299a2e)', Time: '2021-02-18T14:43:22', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '61c833d6-8846-4cf8-bcf5-ccee74900cad'	System	18 Feb 2021 20:43:33
User entered 'No (N)'	System	18 Feb 2021 20:43:33

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2021-02-18T14:43:29', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '61c833d6-8846-4cf8-bcf5-ccee74900cad'	System	18 Feb 2021 20:43:33
User entered '18 Feb 2021 14:43:29'	System	18 Feb 2021 20:43:33

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192942

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192943

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 09:06:40

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

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 (f5f55411d9299a2e)', Time: '2021-02-24T16:38:50-06:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'e4565f8a-f092-4e4c-a96c-857c711f0e3a'	System	24 Feb 2021 22:57:48
User entered 'No (N)'	System	24 Feb 2021 22:57:48

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

Have you been exposed to someone with 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 (f5f55411d9299a2e)', Time: '2021-02-24T16:38:55-06:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'e4565f8a-f092-4e4c-a96c-857c711f0e3a'	System	24 Feb 2021 22:57:48
User entered 'No (N)'	System	24 Feb 2021 22:57:48

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2021-02-24T16:38:59-06:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: 'e4565f8a-f092-4e4c-a96c-857c711f0e3a'	System	24 Feb 2021 22:57:48
User entered '24 Feb 2021 16:38:59'	System	24 Feb 2021 22:57:48

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192948

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192949

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192951

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192952

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 09:06:40

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

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 (f5f55411d9299a2e)', Time: '2021-03-11T22:07:03-06:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '9f5fd076-f585-4997-822f-f2fd9ef12dd2'	System	12 Mar 2021 04:09:02
User entered 'No (N)'	System	12 Mar 2021 04:09:02

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

Have you been exposed to someone with 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 (f5f55411d9299a2e)', Time: '2021-03-11T22:07:06-06:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '9f5fd076-f585-4997-822f-f2fd9ef12dd2'	System	12 Mar 2021 04:09:02
User entered 'No (N)'	System	12 Mar 2021 04:09:02

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2021-03-11T22:07:09-06:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '9f5fd076-f585-4997-822f-f2fd9ef12dd2'	System	12 Mar 2021 04:09:02
User entered '11 Mar 2021 22:07:09'	System	12 Mar 2021 04:09:02

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192957

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192958

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192959

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

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 (f5f55411d9299a2e)', Time: '2021-03-21T21:33:35-05:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '1e0f0507-e3d1-4304-a355-6084aca63f8c'	System	22 Mar 2021 02:33:47
User entered 'No (N)'	System	22 Mar 2021 02:33:47

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

Have you been exposed to someone with 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 (f5f55411d9299a2e)', Time: '2021-03-21T21:33:38-05:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '1e0f0507-e3d1-4304-a355-6084aca63f8c'	System	22 Mar 2021 02:33:47
User entered 'No (N)'	System	22 Mar 2021 02:33:47

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2021-03-21T21:33:41-05:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '1e0f0507-e3d1-4304-a355-6084aca63f8c'	System	22 Mar 2021 02:33:47
User entered '21 Mar 2021 21:33:41'	System	22 Mar 2021 02:33:47

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192963

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192964

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192966

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192967

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192968

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

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 (f5f55411d9299a2e)', Time: '2021-04-03T22:47:13-05:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '3169280a-6fc7-4c69-ace4-573696729719'	System	04 Apr 2021 03:47:24
User entered 'No (N)'	System	04 Apr 2021 03:47:24

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

Have you been exposed to someone with 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 (f5f55411d9299a2e)', Time: '2021-04-03T22:47:17-05:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '3169280a-6fc7-4c69-ace4-573696729719'	System	04 Apr 2021 03:47:24
User entered 'No (N)'	System	04 Apr 2021 03:47:24

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2021-04-03T22:47:20-05:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '3169280a-6fc7-4c69-ace4-573696729719'	System	04 Apr 2021 03:47:24
User entered '03 Apr 2021 22:47:20'	System	04 Apr 2021 03:47:24

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192972

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192973

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192974

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

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 (f5f55411d9299a2e)', Time: '2021-04-08T08:32:53-05:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '69a14fd8-14b4-4d6f-94e1-017747335cbf'	System	08 Apr 2021 13:33:03
User entered 'No (N)'	System	08 Apr 2021 13:33:03

US3042210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:46

Have you been exposed to someone with 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 (f5f55411d9299a2e)', Time: '2021-04-08T08:32:56-05:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '69a14fd8-14b4-4d6f-94e1-017747335cbf'	System	08 Apr 2021 13:33:03
User entered 'No (N)'	System	08 Apr 2021 13:33:03

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2021-04-08T08:32:59-05:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '69a14fd8-14b4-4d6f-94e1-017747335cbf'	System	08 Apr 2021 13:33:03
User entered '08 Apr 2021 08:32:59'	System	08 Apr 2021 13:33:03

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192978

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192982

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192985

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192986

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192988

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192994

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192997

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0192999

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193000

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193002

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193005

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193006

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193017

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193020

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193021

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193023

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193024

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193026

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193027

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193030

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193033

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193036

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193048

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193051

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193057

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193063

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193065

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193068

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193069

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193072

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193074

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193076

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193077

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193078

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193080

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193083

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193084

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193086

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193089

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193092

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193096

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193102

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193105

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193107

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193108

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193111

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193117

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193135

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193136

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193145

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193146

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193148

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193151

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 09:06:40

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US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 09:06:40

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US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 09:06:40

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US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 09:06:40

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US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193213

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 09:06:40

US3042210
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:58:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:06:40
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 09:06:40

FDA-CBER-2022-1614-0193219

US3042210

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:58:46

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 12:43:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2021-03-12T09:47:26-06:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '173eae56-2eb7-4918-9c3b-7f924a26a053'	(b) (4), (b) (6) System	12 Mar 2021 15:47:37
User entered 'No (N)'	System	12 Mar 2021 15:47:37

US3042210

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:58:46

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 12:43:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f5f55411d9299a2e)', Time: '2021-03-12T09:47:31-06:00', User OID: 'PatientReportedOutcome (US3042210)', ODM File OID: '173eae56-2eb7-4918-9c3b-7f924a26a053'	System	12 Mar 2021 15:47:37
User entered '12 Mar 2021 09:47:31'	System	12 Mar 2021 15:47:37

US3042210
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 20:19:29
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:46:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 22:43:41

US3042210
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:29
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:46:20
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 22:43:41

US3042210
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:29
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:46:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Nov 2020 22:43:41

US3042210
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:29
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:46:20
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 22:43:41

FDA-CBER-2022-1614-0193225

US3042210
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 20:19:29
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:46:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 22:43:46

US3042210
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:29
	(b) (4), (b) (6)	
User entered '1'	System	11 Nov 2020 22:43:46

FDA-CBER-2022-1614-0193227

US3042210
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:32:21
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:37:36
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:46:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Dec 2020 06:25:27
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 21:49:32
Query 'Data is required. Please complete.' answered with 'opened in error' (Site from System).	Jamie Thompson (b) (4) (b) (4)	10 Dec 2020 21:05:51
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 20:44:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 20:44:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 20:37:46

FDA-CBER-2022-1614-0193228

US3042210
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:32:21
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:37:36
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:46:51
User entered '10 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 21:49:32
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 20:44:02
User entered '10 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 20:37:46

FDA-CBER-2022-1614-0193229

US3042210
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:32:21
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:37:36
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:46:51
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 21:49:32
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 20:44:02
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	10 Dec 2020 20:37:46

US3042210
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:32:21
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:37:36
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:46:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 20:44:02
User entered 'Left patient message on 10Dec2020 at 0845'	(b) (4), (b) (6)	10 Dec 2020 20:37:46

US3042210
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:35:44
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:37:44
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:47:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 17:31:48

US3042210
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User entered '1'	System	21 Dec 2020 17:31:48

FDA-CBER-2022-1614-0193233

US3042210
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 20:15:39

US3042210
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:00
User entered '11 Jan 2021'	(b) (4), (b) (6)	01 Mar 2021 20:15:39

FDA-CBER-2022-1614-0193235

US3042210
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Mar 2021 20:15:39

US3042210
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 20:15:39

FDA-CBER-2022-1614-0193237

US3042210
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 20:15:50

US3042210
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User entered '1'	System	01 Mar 2021 20:15:50

FDA-CBER-2022-1614-0193239

US3042210
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 20:16:56

US3042210
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:22
User entered '09 Feb 2021'	(b) (4), (b) (6)	01 Mar 2021 20:16:56

US3042210
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Mar 2021 20:16:56

US3042210
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:22
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 20:16:56

FDA-CBER-2022-1614-0193243

US3042210
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 20:17:03

US3042210
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:09:43
User entered '1'	System	01 Mar 2021 20:17:03

FDA-CBER-2022-1614-0193245

US3042210
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:45
User entered 'Yes (Y)'	Jessica Knight (b) (4) (b) (4)	02 Mar 2021 16:17:49

FDA-CBER-2022-1614-0193246

US3042210
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:45
User entered '01 Mar 2021'	Jessica Knight (b) (4) (b) (4)	02 Mar 2021 16:17:49

FDA-CBER-2022-1614-0193247

US3042210
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:45
User entered 'Clinic (Clinic)'	Jessica Knight (b) (4) (b) (4)	02 Mar 2021 16:17:49

FDA-CBER-2022-1614-0193248

US3042210
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:50
User entered 'VISIT4'	(b) (4), (b) (6) System	02 Mar 2021 16:17:49

FDA-CBER-2022-1614-0193249

US3042210
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:58
User entered 'No (N)'	Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:48:05

FDA-CBER-2022-1614-0193250

US3042210
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:58
User entered empty.	Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:48:05

FDA-CBER-2022-1614-0193251

US3042210
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:58
User entered empty.	Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:48:05

FDA-CBER-2022-1614-0193252

US3042210
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:50
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:48:05

FDA-CBER-2022-1614-0193253

US3042210
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:58
User entered empty.	Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:48:05

FDA-CBER-2022-1614-0193254

US3042210
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:58
User entered empty.	Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:48:05

FDA-CBER-2022-1614-0193255

US3042210
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:58
User entered empty.	Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:48:05

US3042210
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:58
User entered empty.	Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:48:05

FDA-CBER-2022-1614-0193257

US3042210
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:50
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:48:05

FDA-CBER-2022-1614-0193258

US3042210
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:58
User entered empty.	Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:48:05

FDA-CBER-2022-1614-0193259

US3042210
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:50
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:48:05

FDA-CBER-2022-1614-0193260

US3042210
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:58
User entered empty.	Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:48:05

US3042210
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:50
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:48:05

FDA-CBER-2022-1614-0193262

US3042210
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:36:58
User entered empty.	Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:48:05

FDA-CBER-2022-1614-0193263

US3042210
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:50
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:48:05

FDA-CBER-2022-1614-0193264

US3042210
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50

FDA-CBER-2022-1614-0193265

US3042210
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50

FDA-CBER-2022-1614-0193266

US3042210
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:58:46
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:38:36
User entered 'No (N)'	Jessica Knight (b) (4) (b) (4)	02 Mar 2021 16:17:55

FDA-CBER-2022-1614-0193267

US3042210
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:58:46
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:38:36
User entered empty.	Jessica Knight (b) (4) (b) (4)	02 Mar 2021 16:17:55

FDA-CBER-2022-1614-0193268

US3042210
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:38:45
User entered 'Yes (Y)'	Jessica Knight (b) (4) (b) (4)	02 Mar 2021 16:18:29

US3042210
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:38:45
User entered '01 Mar 2021'	Jessica Knight (b) (4) (b) (4)	02 Mar 2021 16:18:29

FDA-CBER-2022-1614-0193270

US3042210
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:38:45
User entered '08:23'	Jessica Knight (b) (4) (b) (4)	02 Mar 2021 16:18:29

US3042210
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:50
User entered '01 Mar 2021 08:23'	(b) (4), (b) (6) System	02 Mar 2021 16:18:29

FDA-CBER-2022-1614-0193272

US3042210
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:50
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:38:54
User entered 'Yes (Y)'	Jessica Knight (b) (4) (b) (4)	02 Mar 2021 16:18:38

US3042210
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:50
User entered '1'	(b) (4), (b) (6) System	02 Mar 2021 16:18:38

FDA-CBER-2022-1614-0193274

US3042210
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 21:19:56

FDA-CBER-2022-1614-0193275

US3042210
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
User entered '13 Apr 2021'	(b) (4), (b) (6)	13 Apr 2021 21:19:56

FDA-CBER-2022-1614-0193276

US3042210
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Apr 2021 21:19:56

FDA-CBER-2022-1614-0193277

US3042210
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:38
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:19:56

FDA-CBER-2022-1614-0193278

US3042210
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 21:20:01

FDA-CBER-2022-1614-0193279

US3042210
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 21:20:01

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:39:34
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:50:04

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:39:34
User entered '11 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:50:04

FDA-CBER-2022-1614-0193282

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:39:34
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:50:04

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	11 Jan 2021 17:50:04

FDA-CBER-2022-1614-0193284

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:58:46
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:14
User entered '11 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:50:12

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:58:46
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:57:16
User entered '0'	Rylea Gulick (b) (4) (b) (4)	06 Apr 2021 21:16:06
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:52:14

FDA-CBER-2022-1614-0193286

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:58:46
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:14
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:50:12

US3042210

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

Form: Unblinding

Generated On: 09 Jun 2021 14:58:46

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
User closed query 'Please complete field' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 14:57:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:57:18
Query 'Please complete field' answered with 'entry updated' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	06 Apr 2021 21:16:36
User entered 'Amendment 6 or later (Amendment 6 or later)'	Rylea Gulick (b) (4) (b) (4)	06 Apr 2021 21:16:06
User opened query 'Please complete field' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 20:40:08
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:52:14

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:58:46
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:14
User entered '11 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:50:12

FDA-CBER-2022-1614-0193289

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:58:46
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:14
User entered 'Placebo (Placebo)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:50:12

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:58:46
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:14
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 07:30:25
User entered 'Placebo (Placebo)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:50:12

FDA-CBER-2022-1614-0193291

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:58:46
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:14
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 07:30:25
User entered 'Placebo (Placebo)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:50:12

FDA-CBER-2022-1614-0193292

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:58:46
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:14
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:50:12

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:58:46
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
User entered '1'	(b) (4), (b) (6) System	11 Jan 2021 17:50:12

FDA-CBER-2022-1614-0193294

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:58:46
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
	(b) (4), (b) (6)	
User entered '1'	System	11 Jan 2021 17:50:12

FDA-CBER-2022-1614-0193295

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:58:46
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered missing code ND - Not Done.	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:58:46
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered missing code ND - Not Done.	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:58:46
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
	(b) (4), (b) (6)	
User entered empty.	System	11 Jan 2021 17:51:53
DataPoint set to visible.	System	11 Jan 2021 17:50:12

FDA-CBER-2022-1614-0193298

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:58:46
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered missing code ND - Not Done.	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:58:46
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered missing code ND - Not Done.	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:58:46
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
	(b) (4), (b) (6)	
User entered empty.	System	11 Jan 2021 17:51:53
DataPoint set to visible.	System	11 Jan 2021 17:50:12

FDA-CBER-2022-1614-0193301

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User accepted default value 'Pre-Dose (PREDOSE)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193302

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered '11 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193304

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered '09:00'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
	(b) (4), (b) (6)	
User entered '11 Jan 2021 09:00'	System	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193306

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered '36.8' C	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered 'Oral (Oral)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193309

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered '62'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193310

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
User entered 'bpm'	(b) (4), (b) (6) System	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193311

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered '14'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
	(b) (4), (b) (6)	
User entered 'breaths/min'	System	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193313

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered '130'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193314

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
User entered 'mmHg'	(b) (4), (b) (6) System	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193315

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered '84'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
	(b) (4), (b) (6)	
User entered 'mmHg'	System	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193317

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:58:46
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered missing code ND - Not Done.	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:58:46
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered missing code ND - Not Done.	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:58:46
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
	(b) (4), (b) (6)	
User entered empty.	System	11 Jan 2021 17:51:53
DataPoint set to visible.	System	11 Jan 2021 17:50:12

FDA-CBER-2022-1614-0193320

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User accepted default value 'Post-Dose (POSTDOSE)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193321

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered '11 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193323

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered '10:08'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193324

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
	(b) (4), (b) (6)	
User entered '11 Jan 2021 10:08'	System	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193325

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered '37.1' C	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered 'Oral (Oral)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193327

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193328

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered '69'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193329

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
User entered 'bpm'	(b) (4), (b) (6) System	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193330

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered '16'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193331

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
	(b) (4), (b) (6)	
User entered 'breaths/min'	System	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193332

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered '111'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
User entered 'mmHg'	(b) (4), (b) (6) System	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193334

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:45
User entered '80'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:51:53

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
	(b) (4), (b) (6)	
User entered 'mmHg'	System	11 Jan 2021 17:51:53

FDA-CBER-2022-1614-0193336

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:58:46
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:55
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:52:00

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:58:46
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:40:55
User entered '11 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:52:00

FDA-CBER-2022-1614-0193338

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:41:06
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:52:16

FDA-CBER-2022-1614-0193339

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:41:06
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:52:16

US3042210

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

Form: Exposure

Generated On: 09 Jun 2021 14:58:46

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) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:41:06
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:52:16

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
	(b) (4), (b) (6)	
User entered 'mRNA-1273'	System	11 Jan 2021 17:52:16
DataPoint set to visible.	System	11 Jan 2021 17:50:12

FDA-CBER-2022-1614-0193342

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:41:06
User entered '11 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:52:16

FDA-CBER-2022-1614-0193343

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:41:06
User entered '09:34'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:52:16

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
User entered '11 Jan 2021 09:34'	(b) (4), (b) (6) System	11 Jan 2021 17:52:16

FDA-CBER-2022-1614-0193345

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:41:06
User entered 'Left Arm (LEFT ARM)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:52:16

FDA-CBER-2022-1614-0193346

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 20:41:06
User entered 'ONCE'	System	11 Jan 2021 17:52:16

FDA-CBER-2022-1614-0193347

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
	(b) (4), (b) (6)	
User entered 'INTRAMUSCULAR'	System	11 Jan 2021 17:52:16

FDA-CBER-2022-1614-0193348

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:41:19
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:50:18

FDA-CBER-2022-1614-0193349

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:41:19
User entered '11 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:50:18

FDA-CBER-2022-1614-0193350

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:41:19
User entered '08:42'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:50:18

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
	(b) (4), (b) (6)	
User entered '11 Jan 2021 08:42'	System	11 Jan 2021 17:50:18

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 14:58:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:41:29
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:50:25

FDA-CBER-2022-1614-0193353

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 14:58:46
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:41:29
User entered '11 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:50:25

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 14:58:46
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:41:29
User entered '09:00'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:50:25

FDA-CBER-2022-1614-0193355

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 14:58:46
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
User entered '11 Jan 2021 09:00'	(b) (4), (b) (6) System	11 Jan 2021 17:50:25

FDA-CBER-2022-1614-0193356

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:46:05
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:41:37
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 17:50:27

US3042210
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:46:05
User entered '1'	(b) (4), (b) (6) System	11 Jan 2021 17:50:27

FDA-CBER-2022-1614-0193358

US3042210
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:32:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:41:51
User entered 'Yes (Y)'	Jessica Knight (b) (4) (b) (4)	19 Jan 2021 21:06:02

US3042210
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:32:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:41:51
User entered '19 Jan 2021'	Jessica Knight (b) (4) (b) (4)	19 Jan 2021 21:06:02

US3042210
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:32:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:41:51
User entered 'Contact Made (CONTACT MADE)'	Jessica Knight (b) (4) (b) (4)	19 Jan 2021 21:06:02

US3042210
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:32:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:41:51
User entered empty.	Jessica Knight (b) (4) (b) (4)	19 Jan 2021 21:06:02

FDA-CBER-2022-1614-0193362

US3042210
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:32:31
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:10
User entered 'Yes (Y)'	Jessica Knight (b) (4) (b) (4)	19 Jan 2021 21:05:49

US3042210
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:31
User entered '1'	(b) (4), (b) (6) System	19 Jan 2021 21:05:49

FDA-CBER-2022-1614-0193364

US3042210
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:31
	(b) (4), (b) (6)	
User entered '1'	System	19 Jan 2021 21:05:49
DataPoint set to visible.	System	19 Jan 2021 21:05:49

FDA-CBER-2022-1614-0193365

US3042210
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:34
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:02

US3042210
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:34
User entered '08 Feb 2021'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:02

FDA-CBER-2022-1614-0193367

US3042210
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:34
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:02

US3042210
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:14
User entered 'OLD29'	(b) (4), (b) (6) System	08 Feb 2021 20:14:02

FDA-CBER-2022-1614-0193369

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User accepted default value 'Pre-Dose (PREDOSE)'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193370

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered '08 Feb 2021'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered '08:20'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:14
User entered '08 Feb 2021 08:20'	(b) (4), (b) (6) System	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193374

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered '36.7' C	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered 'Oral (Oral)'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193376

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193377

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered '63'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193378

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:14
User entered 'bpm'	(b) (4), (b) (6) System	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193379

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered '12'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:14
User entered 'breaths/min'	(b) (4), (b) (6) System	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193381

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered '138'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:14
	(b) (4), (b) (6)	
User entered 'mmHg'	System	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193383

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered '86'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193384

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:14
User entered 'mmHg'	(b) (4), (b) (6) System	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193385

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User accepted default value 'Post-Dose (POSTDOSE)'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193386

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered '08 Feb 2021'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193388

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered '09:35'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193389

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:14
User entered '08 Feb 2021 09:35'	(b) (4), (b) (6) System	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193390

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered '36.6' C	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered 'Oral (Oral)'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193392

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered '76'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193394

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:14
User entered 'bpm'	(b) (4), (b) (6) System	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193395

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered '12'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193396

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:14
User entered 'breaths/min'	(b) (4), (b) (6) System	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193397

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered '120'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193398

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:14
User entered 'mmHg'	(b) (4), (b) (6) System	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193399

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:42
User entered '80'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193400

US3042210
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:14
User entered 'mmHg'	(b) (4), (b) (6) System	08 Feb 2021 20:14:32

FDA-CBER-2022-1614-0193401

US3042210
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:58:46
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:56
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:36

FDA-CBER-2022-1614-0193402

US3042210
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:58:46
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:42:56
User entered '08 Feb 2021'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:36

US3042210
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:43:05
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:49

US3042210
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:43:05
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:49

US3042210
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46

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) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:43:05
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:49

FDA-CBER-2022-1614-0193406

US3042210
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:14
	(b) (4), (b) (6)	
User entered 'mRNA-1273'	System	08 Feb 2021 20:14:49
DataPoint set to visible.	System	19 Jan 2021 21:05:49

FDA-CBER-2022-1614-0193407

US3042210
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:43:05
User entered '08 Feb 2021'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:49

US3042210
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:43:05
User entered '09:04'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:49

FDA-CBER-2022-1614-0193409

US3042210
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:14
User entered '08 Feb 2021 09:04'	(b) (4), (b) (6) System	08 Feb 2021 20:14:49

FDA-CBER-2022-1614-0193410

US3042210
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:43:05
User entered 'Left Arm (LEFT ARM)'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:49

FDA-CBER-2022-1614-0193411

US3042210
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:14
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 20:43:05
User entered 'ONCE'	System	08 Feb 2021 20:14:49

US3042210
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:58:46
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:14
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	08 Feb 2021 20:14:49

FDA-CBER-2022-1614-0193413

US3042210
Folder: OL-D29 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:15:14
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:43:18
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	08 Feb 2021 20:14:51

US3042210
Folder: OL-D29 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:14
User entered '1'	(b) (4), (b) (6) System	08 Feb 2021 20:14:51

FDA-CBER-2022-1614-0193415

US3042210
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 03:45:39
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:43:34
User entered 'Yes (Y)'	Jamie Thompson (b) (4) (b) (4)	15 Feb 2021 21:56:05

FDA-CBER-2022-1614-0193416

US3042210
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 03:45:39
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:43:34
User entered '15 Feb 2021'	Jamie Thompson (b) (4) (b) (4)	15 Feb 2021 21:56:05

FDA-CBER-2022-1614-0193417

US3042210
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 03:45:39
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:43:34
User entered 'Contact Made (CONTACT MADE)'	Jamie Thompson (b) (4) (b) (4)	15 Feb 2021 21:56:05

FDA-CBER-2022-1614-0193418

US3042210
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:58:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 03:45:39
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:43:34
User entered empty.	Jamie Thompson (b) (4) (b) (4)	15 Feb 2021 21:56:05

FDA-CBER-2022-1614-0193419

US3042210
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 03:45:39
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:43:43
User entered 'Yes (Y)'	Jamie Thompson (b) (4) (b) (4)	15 Feb 2021 21:56:10

FDA-CBER-2022-1614-0193420

US3042210
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:58:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:45:39
User entered '1'	(b) (4), (b) (6) System	15 Feb 2021 21:56:10

FDA-CBER-2022-1614-0193421

US3042210
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:44:16
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:11:18

US3042210
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:44:16
User entered '15 Mar 2021'	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:11:18

US3042210
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:44:16
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:11:18

US3042210
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:58:46
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:36
	(b) (4), (b) (6)	
User entered 'OLD57'	System	15 Mar 2021 19:11:18

FDA-CBER-2022-1614-0193425

US3042210
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:44:43
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:11:28

US3042210
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:44:43
User entered '15 Mar 2021'	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:11:28

FDA-CBER-2022-1614-0193427

US3042210
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:44:43
User entered '08:05'	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:11:28

FDA-CBER-2022-1614-0193428

US3042210
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:36
User entered '15 Mar 2021 08:05'	(b) (4), (b) (6) System	15 Mar 2021 19:11:28

FDA-CBER-2022-1614-0193429

US3042210
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:44:43
User entered '37.0' C	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:11:28

US3042210
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:44:43
User entered 'Oral (Oral)'	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:11:28

US3042210
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:44:43
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:11:28

FDA-CBER-2022-1614-0193432

US3042210
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:44:43
User entered '63'	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:11:28

FDA-CBER-2022-1614-0193433

US3042210
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:36
User entered 'bpm'	(b) (4), (b) (6) System	15 Mar 2021 19:11:28

FDA-CBER-2022-1614-0193434

US3042210
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:44:43
User entered '14'	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:11:28

FDA-CBER-2022-1614-0193435

US3042210
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:36
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Mar 2021 19:11:28

FDA-CBER-2022-1614-0193436

US3042210
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:44:43
User entered '132'	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:11:28

FDA-CBER-2022-1614-0193437

US3042210
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:36
	(b) (4), (b) (6)	
User entered 'mmHg'	System	15 Mar 2021 19:11:28

FDA-CBER-2022-1614-0193438

US3042210
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:44:43
User entered '78'	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:11:28

FDA-CBER-2022-1614-0193439

US3042210
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:36
User entered 'mmHg'	(b) (4), (b) (6) System	15 Mar 2021 19:11:28

FDA-CBER-2022-1614-0193440

US3042210
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36

FDA-CBER-2022-1614-0193441

US3042210
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:58:46
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36

FDA-CBER-2022-1614-0193442

US3042210
Folder: OL-D57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:58:46
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:44:59
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:11:30

US3042210
Folder: OL-D57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:58:46
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:44:59
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:11:30

FDA-CBER-2022-1614-0193444

US3042210
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:09
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:11:46

US3042210
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:09
User entered '15 Mar 2021'	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:11:46

FDA-CBER-2022-1614-0193446

US3042210
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:01:36
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:09
User entered '08:15'	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:11:46

FDA-CBER-2022-1614-0193447

US3042210
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:58:46
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:36
User entered '15 Mar 2021 08:15'	(b) (4), (b) (6) System	15 Mar 2021 19:11:46

FDA-CBER-2022-1614-0193448

US3042210
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 14:58:46
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 May 2021 06:53:21
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:53:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	07 Nov 2020 16:55:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:31:14

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
AEID

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:27
User entered 'USA-US052-2020-mRNA-1273-P301000020'	System	01 Dec 2020 16:14:19
User entered 'New'	(b) (4), (b) (6)	01 Dec 2020 16:14:19

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User coded data point as SOC: Nervous system disorders, HLGT: Nervous system neoplasms benign, HLT: Nervous system cysts and polyps, PT: Arachnoid cyst, LLT: Arachnoid cyst - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:44:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:44:53
User closed query 'PV Query: Please correct event term to growing/worsening of arachnoid cyst on lumbar spine. ' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 18:19:38
Data point term sent to Coder	System	08 Dec 2020 20:41:27
Query 'PV Query: Please correct event term to growing/worsening of arachnoid cyst on lumbar spine. ' answered with 'ENTRY UPDATED' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 20:40:48
Coding entries removed.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 20:40:42
User entered 'GROWING/WORSENING OF ARACHNOID CYST ON LUMBAR SPINE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 20:40:42
User opened query 'PV Query: Please correct event term to growing/worsening of arachnoid cyst on lumbar spine. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 20:39:20
User coded data point as SOC: Nervous system disorders, HLGT: Nervous system neoplasms benign, HLT: Nervous system cysts and polyps, PT: Arachnoid cyst, LLT: Arachnoid cyst - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 03:31:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 03:31:39
Data point term sent to Coder	System	11 Nov 2020 23:17:50
User entered 'GROWING/WORSENING OF ARACHNOID CYST ON LUMBER SPINE'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

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US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '01 Nov 2020'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

FDA-CBER-2022-1614-0193455

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

FDA-CBER-2022-1614-0193456

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 23:17:01

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '03 Nov 2020'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

FDA-CBER-2022-1614-0193459

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

FDA-CBER-2022-1614-0193460

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 23:17:01

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Severity

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User closed query 'PV Query: Please confirm the severity, since the event lead to hospitalization.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 14:19:08
Query 'PV Query: Please confirm the severity, since the event lead to hospitalization.' answered with 'THIS IS SEVERITY PER PI' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 15:07:45
User opened query 'PV Query: Please confirm the severity, since the event lead to hospitalization.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 21:13:15
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 21:29:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Nov 2020 21:29:24
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	30 Nov 2020 21:29:24
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 23:17:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	30 Nov 2020 21:30:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	30 Nov 2020 21:30:57
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	30 Nov 2020 21:29:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Death

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

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US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

FDA-CBER-2022-1614-0193465

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '1' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	30 Nov 2020 21:29:24
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '03 Nov 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	30 Nov 2020 21:29:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '06 Nov 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	30 Nov 2020 21:29:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

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US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered 'No (N)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	30 Nov 2020 21:29:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

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US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

FDA-CBER-2022-1614-0193471

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

FDA-CBER-2022-1614-0193472

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 21:29:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Nov 2020 21:29:24
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	30 Nov 2020 21:29:24
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 23:17:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:59:53
DataPoint Un-verified.	Jamie Thompson (b) (4) (b) (4)	11 Jan 2021 19:27:16
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jamie Thompson (b) (4)	11 Jan 2021 19:27:16
User closed query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly. ' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 21:30:40
Query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly. ' answered with 'THIS IS NOT APPLICABLE PER PI DISCRETION.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 16:10:04
User opened query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly. ' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 13:57:49
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User closed query 'PV Query: Please provide the rationale why the event was assessed as Not applicable to the procedure. ' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 17:43:58
Query 'PV Query: Please provide the rationale why the event was assessed as Not applicable to the procedure. ' answered with 'not applicable per pi' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 15:42:05

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Relationship to Study Procedure

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the rationale why the event was assessed as Not applicable to the procedure. ' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:19:21
User closed query 'Per CDM: AE started after first dose, yet Not applicable is selected for relationship to study procedure. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 07:04:52
Query 'Per CDM: AE started after first dose, yet Not applicable is selected for relationship to study procedure. Please review and update as appropriate. ' answered with 'NOT APPLICABLE PER PI' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 14:08:15
User opened query 'Per CDM: AE started after first dose, yet Not applicable is selected for relationship to study procedure. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 10:24:53
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 21:29:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Nov 2020 21:29:24
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	30 Nov 2020 21:29:24
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 23:17:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

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US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
Query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly. ' canceled (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 13:57:40
User opened query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly. ' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 13:57:33
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
None

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

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US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:52:21
User closed query 'Please answer the query just as the one answered below, but put in "pain meds" instead of "antibiotic"' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 22:51:54
Query 'Please answer the query just as the one answered below, but put in "pain meds" instead of "antibiotic"' answered with "PER SUMMARY, PAIN MED WAS GIVEN, HOWEVER, DOSAGE OR NAME WAS NOT GIVEN' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	22 Apr 2021 20:15:36
User opened query 'Please answer the query just as the one answered below, but put in "pain meds" instead of "antibiotic"' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:57:06
User closed query 'Please address the pain meds given, antibiotic was addressed in the query below.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:57:06
Query 'Please address the pain meds given, antibiotic was addressed in the query below.' answered with 'CON MED WILL BE UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:26:24
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 18:04:00
User opened query 'Please address the pain meds given, antibiotic was addressed in the query below.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:03:48
User closed query 'Please update, discharge summary states there was pain meds given' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:00:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:00:42
Query 'Please update, discharge summary states there was pain meds given' answered with 'PER SUMMARY, ANITBIOTIC WAS GIVEN, HOWEVER, DOSAGE OR NAME WAS NOT GIVEN.' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 19:18:08
User entered '1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 19:17:46
User opened query 'Please update, discharge summary states there was pain meds given' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:19:48
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 15:05:28

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

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US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '1'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

FDA-CBER-2022-1614-0193481

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Outcome

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Narrative

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:01:22
User closed query 'Per your response no other treatment was given, however, antibiotics are noted on the discharge summary' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:01:18
User closed query 'Per your response no other treatment was given, however, pain meds are noted on the discharge summary. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:01:06
Query 'Per your response no other treatment was given, however, antibiotics are noted on the discharge summary' answered with 'PER SUMMARY, ANTIBIOTICS WERE GIVEN, HOWEVER, DOSAGE OR NAME WAS NOT.' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 19:19:32
Query 'Per your response no other treatment was given, however, pain meds are noted on the discharge summary. ' answered with 'PER SUMMARY, ANTIBIOTICS WERE GIVEN, HOWEVER, DOSAGE OR NAME NOT GIVEN.' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 19:19:13
User opened query 'Per your response no other treatment was given, however, antibiotics are noted on the discharge summary' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:33:09
User opened query 'Per your response no other treatment was given, however, pain meds are noted on the discharge summary. ' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:21:30
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 15:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User closed query 'PV Query: "bilateral lower leg neuralgia" was listed as the indication for gabapentin and Cymbalta. Please confirm if bilateral lower leg neuralgia was experienced and should be added as an AE/SAE or consider updating the indication.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 14:19:22
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 14:18:44

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 14:18:31
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 14:18:26
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 14:18:18
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)	29 Dec 2020 14:18:13
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'RECORDS ARE BEING SENT.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 15:12:21
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 'INFORMATION NOT AVAILABLE.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 15:11:34
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'NO UNDERLAYING RISK FACTORS.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 15:11:24
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'NONE TO PROVIDE.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 15:11:13

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Narrative

Audit	User	Time (GMT)
Query 'PV Query: "bilateral lower leg neuralgia" was listed as the indication for gabapentin and Cymbalta. Please confirm if bilateral lower leg neuralgia was experienced and should be added as an AE/SAE or consider updating the indication.' answered with 'AE WAS UPDATED TO REFLECT THIS.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 15:11:06
Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' answered with 'SUBJECT WAS PUT ON 72 HOUR BED REST POST OP.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 15:09:47
User opened query 'PV Query: "bilateral lower leg neuralgia" was listed as the indication for gabapentin and Cymbalta. Please confirm if bilateral lower leg neuralgia was experienced and should be added as an AE/SAE or consider updating the indication.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 15:34:47
User closed query 'PV Query: Did the subject have a medical history of arachnoid cyst on lumbar spine? If so, please add to subject's medical history.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 16:51:24
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 21:10:16
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 21:09:51
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 21:08:59
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 21:06:24
Query 'PV Query: Did the subject have a medical history of arachnoid cyst on lumbar spine? If so, please add to subject's medical history.' answered with 'yes. added to med history' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:11:45

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Was there any other treatment besides surgery? If so,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)	10 Dec 2020 14:28:29
Query 'PV Query: Was there any other treatment besides surgery? If so,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 'NO OTHER TREATMENTS BESIDES SURGER.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 15:03:11
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 20:40:49
User opened query 'PV Query: Was there any other treatment besides surgery? If so,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)	08 Dec 2020 20:40:25
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 20:39:47
User opened query 'PV Query: Did the subject have a medical history of arachnoid cyst on lumbar spine? If so, please add to subject's medical history.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 20:38:31
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)	08 Dec 2020 20:38:06
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Nov 2020 21:32:15

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Narrative

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	30 Nov 2020 21:32:15
User entered 'Patient had surgical excision of arachnoid cyst on lumbar spine and was in patient at surgical center from 03Nov-06NOV' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	30 Nov 2020 21:32:15
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Nov 2020 21:30:57
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:01

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US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	30 Nov 2020 21:30:57
User entered '0'	System	11 Nov 2020 23:17:01

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 23:17:01

US3042210
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:58:46
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	30 Nov 2020 21:29:24

US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Neuralgia, LLT: Peripheral neuropathic pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 16:49:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 16:49:57
Data point term sent to Coder	System	11 Dec 2020 16:12:56
User entered 'BILATERAL LOWER LEG NEURALGIA'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '03 Nov 2020'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Dec 2020 16:12:23

US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
User closed query 'Please review and update if required, thanks ' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 22:53:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:53:02
Query 'Please review and update if required, thanks ' answered with 'THIS IS STILL ONOING' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	22 Apr 2021 20:16:19
User opened query 'Please review and update if required, thanks ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:09:57
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 15:09:04
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:53:27
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 15:09:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Dec 2020 16:12:23

US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Severity

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 16:36:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Dec 2020 16:36:28
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	28 Dec 2020 16:36:28
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 16:12:23
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Death

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

FDA-CBER-2022-1614-0193505

US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 16:35:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Dec 2020 16:35:55
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	28 Dec 2020 16:35:55
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 16:12:23
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 16:35:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Dec 2020 16:35:55
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	28 Dec 2020 16:35:55
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 16:12:23
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
None

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '1'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Outcome

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:53:56
User closed query 'Please update if required, thanks' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 22:53:44
Query 'Please update if required, thanks' answered with 'THIS IS STILL ONGOING' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	22 Apr 2021 20:16:41
User opened query 'Please update if required, thanks' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:10:36
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 15:08:47
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Narrative

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:54:11
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:12:23

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US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	11 Dec 2020 16:12:23

US3042210
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:58:46
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	11 Dec 2020 16:12:23

US3042210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:58:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 May 2021 06:53:21
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:07
User closed query 'Per CDM, re-query of a system query on Diary Dose 2 (1), Temperature day, Day 5: Per the participant response, medication was taken to treat pain or fever. There was a response that the participant was contacted, however there is no matching medication on the eCRF for the same timepoint. Please update the ConMed eCRF as appropriate or clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 11:55:02
Query 'Per CDM, re-query of a system query on Diary Dose 2 (1), Temperature day, Day 5: Per the participant response, medication was taken to treat pain or fever. There was a response that the participant was contacted, however there is no matching medication on the eCRF for the same timepoint. Please update the ConMed eCRF as appropriate or clarify. ' answered with 'TYLENOL WAS TAKEN' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 14:06:41
User opened query 'Per CDM, re-query of a system query on Diary Dose 2 (1), Temperature day, Day 5: Per the participant response, medication was taken to treat pain or fever. There was a response that the participant was contacted, however there is no matching medication on the eCRF for the same timepoint. Please update the ConMed eCRF as appropriate or clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:04:10
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:29:16

US3042210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:46

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 19:31:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 19:31:11
Data point term sent to Coder	System	17 Aug 2020 19:30:12
User entered 'ATENOLOL'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:29:36

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:58:46
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:29:36

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:58:46
Indication

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'HYPERTENSION'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:29:36

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US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:58:46
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered '50'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:29:36

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:58:46
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:29:36

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:58:46
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:29:36

FDA-CBER-2022-1614-0193532

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:58:46
Frequency

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:29:36

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:58:46
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:29:36

FDA-CBER-2022-1614-0193534

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:58:46
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:29:36

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:58:46
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:29:36

FDA-CBER-2022-1614-0193536

US3042210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:46

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 09:41:20
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:29:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 19:29:36
User entered 'UN UNK 2010'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:29:36

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:58:46
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:29:36

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:58:46
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:29:36

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:58:46
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:29:36

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US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:58:46
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:29:36

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:58:46
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 19:29:36

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:58:46
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 19:29:36

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:58:46
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 19:29:36

US3042210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:58:46

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
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)	17 Aug 2020 19:31:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 19:31:11
Data point term sent to Coder	System	17 Aug 2020 19:30:13
User entered 'LISINOPRIL'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:05

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:58:46
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:05

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US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:58:46
Indication

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'HYPERTENSION'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:05

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:58:46
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered '40'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:05

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US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:58:46
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:05

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:58:46
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:05

FDA-CBER-2022-1614-0193550

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:58:46
Frequency

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:05

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:58:46
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:05

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:58:46
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:05

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:58:46
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:05

FDA-CBER-2022-1614-0193554

US3042210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:58:46

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 09:41:29
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:10
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	17 Aug 2020 19:30:05
User entered 'UN UNK 2017'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:05

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:58:46
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:05

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:58:46
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:05

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:58:46
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:05

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US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:58:46
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:05

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:58:46
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 19:30:05

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:58:46
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 19:30:05

FDA-CBER-2022-1614-0193561

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:58:46
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 19:30:05

FDA-CBER-2022-1614-0193562

US3042210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:58:46

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 19:32:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 19:32:09
Data point term sent to Coder	System	17 Aug 2020 19:31:18
User entered 'LIPITOR'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:28

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:58:46
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:28

FDA-CBER-2022-1614-0193564

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:58:46
Indication

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'HYPERLIPIDEMIA'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:28

FDA-CBER-2022-1614-0193565

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:58:46
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered '10'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:28

FDA-CBER-2022-1614-0193566

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:58:46
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:28

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:58:46
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:28

FDA-CBER-2022-1614-0193568

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:58:46
Frequency

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:28

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:58:46
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:28

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:58:46
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:28

FDA-CBER-2022-1614-0193571

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:58:46
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:28

FDA-CBER-2022-1614-0193572

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:58:46
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2017). Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 11:16:24
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2017). Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'REVIEWED AND UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 00:04:08
User entered 'UN UNK 2017' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 00:03:55
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2017). Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 09:27:06
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 09:41:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:32
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	17 Aug 2020 19:30:28
User entered 'UN UNK 2010'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:28

FDA-CBER-2022-1614-0193573

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:58:46
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:28

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:58:46
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:28

FDA-CBER-2022-1614-0193575

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:58:46
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:28

FDA-CBER-2022-1614-0193576

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:58:46
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:28

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:58:46
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 19:30:28

FDA-CBER-2022-1614-0193578

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:58:46
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 19:30:28

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:58:46
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 19:30:28

US3042210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:58:46

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 19:32:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 19:32:10
Data point term sent to Coder	System	17 Aug 2020 19:31:18
User entered 'LEVOTHYROXINE'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:58

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:58:46
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:58

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:58:46
Indication

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'HYPOTHYROIDISM'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:58

FDA-CBER-2022-1614-0193583

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:58:46
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered '50'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:58

FDA-CBER-2022-1614-0193584

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:58:46
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'ug (ug)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:58

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:58:46
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:58

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:58:46
Frequency

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:58

FDA-CBER-2022-1614-0193587

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:58:46
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:58

FDA-CBER-2022-1614-0193588

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:58:46
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:58

FDA-CBER-2022-1614-0193589

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:58:46
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:58

US3042210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:58:46

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 09:41:56
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:31:04
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 19:30:58
User entered 'UN UNK 2015'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:58

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:58:46
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:58

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:58:46
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:58

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:58:46
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:58

FDA-CBER-2022-1614-0193594

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:58:46
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:30:58

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:58:46
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 19:30:58

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:58:46
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 19:30:58

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:58:46
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 19:30:58

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:58:46
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:41:33
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 14:07:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 14:07:54
Data point term sent to Coder	System	01 Oct 2020 14:07:23
User entered 'TYLENOL'	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 14:07:21

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:58:46
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:41:33
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 14:07:21

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:58:46
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:41:33
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:34:43
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'AE LOG UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	07 Nov 2020 16:59:16

US3042210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:58:46

Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:15:14
User entered 'SOLICITED SYMPTOM-HEADACHE'	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 14:07:21

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:58:46
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:41:33
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered '1000'	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 14:07:21

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:58:46
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:41:33
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 14:07:21

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:58:46
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:41:33
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 14:07:21

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:58:46
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:41:33
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'as needed (PRN)'	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 14:07:21

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:58:46
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:41:33
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 14:07:21

FDA-CBER-2022-1614-0193607

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:58:46
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:41:33
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 14:07:21

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:58:46
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:41:33
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 14:07:21

FDA-CBER-2022-1614-0193609

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:58:46
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:41:33
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered '17 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 14:07:21

FDA-CBER-2022-1614-0193610

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:58:46
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:41:33
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered '0'	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 14:07:21

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:58:46
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:41:33
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 14:07:21

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:58:46
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:41:33
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered '20 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 14:07:21

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:58:46
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:41:33
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 14:07:21

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:58:46
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:41:33
User entered empty.	(b) (4), (b) (6) System	01 Oct 2020 14:07:21

FDA-CBER-2022-1614-0193615

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:58:46
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:41:33
User entered empty.	(b) (4), (b) (6) System	01 Oct 2020 14:07:21

FDA-CBER-2022-1614-0193616

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:58:46
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:41:33
User entered empty.	(b) (4), (b) (6) System	01 Oct 2020 14:07:21

FDA-CBER-2022-1614-0193617

US3042210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:58:46

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 16:54:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 16:54:50
Data point term sent to Coder	System	11 Dec 2020 16:13:57
User entered 'GABAPENTIN'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:19

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:58:46
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:19

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:58:46
Indication

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'BILATERAL LOWER LEG NEURALGIA'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:19

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:58:46
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered '800'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:19

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:58:46
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:19

FDA-CBER-2022-1614-0193622

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:58:46
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:19

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:58:46
Frequency

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'three times daily (TID)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:19

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:58:46
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:19

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:58:46
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:19

FDA-CBER-2022-1614-0193626

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:58:46
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:19

FDA-CBER-2022-1614-0193627

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:58:46
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered '03 Nov 2020'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:19

FDA-CBER-2022-1614-0193628

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:58:46
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:19

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:58:46
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:19

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:58:46
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:19

FDA-CBER-2022-1614-0193631

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:58:46
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:19

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:58:46
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '3'	System	11 Dec 2020 16:13:19

FDA-CBER-2022-1614-0193633

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:58:46
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Dec 2020 16:13:19

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:58:46
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Dec 2020 16:13:19

US3042210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:58:46

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: DULOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: CYMBALTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 16:52:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 16:52:52
Data point term sent to Coder	System	11 Dec 2020 16:13:57
User entered 'CYMBALTA'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:50

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:58:46
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:50

FDA-CBER-2022-1614-0193637

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:58:46
Indication

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'BILATERAL LOWER LEG NEURALGIA'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:50

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:58:46
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered '60'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:50

FDA-CBER-2022-1614-0193639

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:58:46
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:50

FDA-CBER-2022-1614-0193640

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:58:46
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:50

FDA-CBER-2022-1614-0193641

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:58:46
Frequency

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:50

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:58:46
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:50

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:58:46
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:50

FDA-CBER-2022-1614-0193644

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:58:46
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:50

FDA-CBER-2022-1614-0193645

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:58:46
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered '03 Nov 2020'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:50

FDA-CBER-2022-1614-0193646

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:58:46
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:50

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:58:46
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:50

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:58:46
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:50

FDA-CBER-2022-1614-0193649

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:58:46
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:56:52
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 16:13:50

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:58:46
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Dec 2020 16:13:50

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:58:46
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Dec 2020 16:13:50

FDA-CBER-2022-1614-0193652

US3042210
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:58:46
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Dec 2020 16:13:50

US3042210
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 09 Jun 2021 14:58:46
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 May 2021 06:53:21
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:57:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:10
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Aug 2020 19:31:09

US3042210
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 14:58:46
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:57:32
User entered '03 Nov 2020'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:39

FDA-CBER-2022-1614-0193655

US3042210
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 14:58:46
Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:57:32
User entered 'SURGICAL EXCISION OF ARACHNOID CYST OVER LUMBER SPINE'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:39

FDA-CBER-2022-1614-0193656

US3042210
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 14:58:46
Indication

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:57:32
User entered 'Adverse Event (AE)'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:39

FDA-CBER-2022-1614-0193657

US3042210
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 14:58:46
If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:57:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 23:17:39

FDA-CBER-2022-1614-0193658

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
SAEID

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'USA-US052-2020-MRNA-1273-P301000020'	System	01 Dec 2020 16:14:19

FDA-CBER-2022-1614-0193659

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Serious

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Yes (Y)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Death

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

FDA-CBER-2022-1614-0193662

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Yes (Y)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

FDA-CBER-2022-1614-0193664

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:35
User closed query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:57:29
Query 'Try changing it again, I think they fixed it' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:07
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:01
User opened query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:20
User closed query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:20
Un-reviewed for Safety.	System	12 Jan 2021 18:25:05
User entered 'Meagan'	System	12 Jan 2021 18:25:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:24:52
Query 'Please change to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:22
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User opened query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:50:19
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Meagan'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:37
User closed query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:57:18
Query 'Try changing it again, I think they fixed it' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:12
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:01
User opened query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:44
User closed query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:44
Un-reviewed for Safety.	System	12 Jan 2021 18:25:05
User entered 'Miller'	System	12 Jan 2021 18:25:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:24:52
Query 'Please change to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:26
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User opened query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:50:39
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Miller'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:44
User closed query 'Please add address, should be current address because SAE occurred after Nov 1 move, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:57:42
Query 'Please add address, should be current address because SAE occurred after Nov 1 move, thanks' answered with 'ADDRESS ADDED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:39
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
User opened query 'Please add address, should be current address because SAE occurred after Nov 1 move, thanks' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:58:47
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:39
User closed query 'Address should be the updated one because this SAE happened after the move. Thanks' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:57:21
Query 'Address should be the updated one because this SAE happened after the move. Thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:19:01
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User opened query 'Address should be the updated one because this SAE happened after the move. Thanks' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:41:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered '330 dakota dunes suite400'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:46
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:41
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'North sioux'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:49
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'IA'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:51
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:46
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered '57049'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 18:19:17
User entered 'US'	System	01 Dec 2020 16:14:48

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 16:37:48
User entered '4'	System	12 Jan 2021 18:25:05
User entered '3'	System	14 Dec 2020 17:02:49
User entered '2'	System	09 Dec 2020 18:19:26
User entered '1'	System	01 Dec 2020 16:14:48

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
SAEID

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'USA-US052-2020-MRNA-1273-P301000020'	System	01 Dec 2020 16:14:19

FDA-CBER-2022-1614-0193675

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Serious

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Yes (Y)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Death

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

FDA-CBER-2022-1614-0193678

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Yes (Y)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:35
User closed query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:57:29
Query 'Try changing it again, I think they fixed it' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:07
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:01
User opened query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:20
User closed query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:20
Un-reviewed for Safety.	System	12 Jan 2021 18:25:05
User entered 'Meagan'	System	12 Jan 2021 18:25:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:24:52
Query 'Please change to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:22
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User opened query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:50:19
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Meagan'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:37
User closed query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:57:18
Query 'Try changing it again, I think they fixed it' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:12
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:01
User opened query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:44
User closed query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:44
Un-reviewed for Safety.	System	12 Jan 2021 18:25:05
User entered 'Miller'	System	12 Jan 2021 18:25:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:24:52
Query 'Please change to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:26
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User opened query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:50:39
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Miller'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:44
User closed query 'Please add address, should be current address because SAE occurred after Nov 1 move, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:57:42
Query 'Please add address, should be current address because SAE occurred after Nov 1 move, thanks' answered with 'ADDRESS ADDED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:39
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
User opened query 'Please add address, should be current address because SAE occurred after Nov 1 move, thanks' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:58:47
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:39
User closed query 'Address should be the updated one because this SAE happened after the move. Thanks' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:57:21
Query 'Address should be the updated one because this SAE happened after the move. Thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:19:01
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User opened query 'Address should be the updated one because this SAE happened after the move. Thanks' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:41:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered '330 dakota dunes suite400'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:46
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:41
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'North sioux'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:49
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'IA'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:51
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:46
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered '57049'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 18:19:17
User entered 'US'	System	01 Dec 2020 16:14:48

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 16:37:48
User entered '4'	System	12 Jan 2021 18:25:05
User entered '3'	System	14 Dec 2020 17:02:49
User entered '2'	System	09 Dec 2020 18:19:26
User entered '1'	System	01 Dec 2020 16:14:48

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 14:58:46
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
User entered '01/Dec/2020 11:14'	System	01 Dec 2020 16:14:48

US3042210

Folder: SAE USA-US052-2020-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:58:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 18:19:17
User entered '1'	(b) (4), (b) (6)	01 Dec 2020 16:14:48

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
SAEID

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'USA-US052-2020-MRNA-1273-P301000020'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Serious

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Yes (Y)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Death

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

FDA-CBER-2022-1614-0193696

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Yes (Y)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:35
User closed query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:57:29
Query 'Try changing it again, I think they fixed it' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:07
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:01
User opened query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:20
User closed query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:20
Un-reviewed for Safety.	System	12 Jan 2021 18:25:05
User entered 'Meagan'	System	12 Jan 2021 18:25:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:24:52
Query 'Please change to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:22
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User opened query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:50:19
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Meagan'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:37
User closed query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:57:18
Query 'Try changing it again, I think they fixed it' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:12
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:01
User opened query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:44
User closed query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:44
Un-reviewed for Safety.	System	12 Jan 2021 18:25:05
User entered 'Miller'	System	12 Jan 2021 18:25:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:24:52
Query 'Please change to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:26
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User opened query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:50:39
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Miller'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:44
User closed query 'Please add address, should be current address because SAE occurred after Nov 1 move, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:57:42
Query 'Please add address, should be current address because SAE occurred after Nov 1 move, thanks' answered with 'ADDRESS ADDED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:39
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
User opened query 'Please add address, should be current address because SAE occurred after Nov 1 move, thanks' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:58:47
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:39
User closed query 'Address should be the updated one because this SAE happened after the move. Thanks' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:57:21
Query 'Address should be the updated one because this SAE happened after the move. Thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:19:01
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User opened query 'Address should be the updated one because this SAE happened after the move. Thanks' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:41:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered '330 dakota dunes suite400'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:46
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:41
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'North sioux'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:49
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'IA'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:51
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:46
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered '57049'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 18:19:17
User entered 'US'	System	01 Dec 2020 16:14:48

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 16:37:48
User entered '4'	System	12 Jan 2021 18:25:05
User entered '3'	System	14 Dec 2020 17:02:49
User entered '2'	System	09 Dec 2020 18:19:26
User entered '1'	System	01 Dec 2020 16:14:48

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 14:58:46
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
User entered '09/Dec/2020 18:19'	System	09 Dec 2020 18:19:26

US3042210

Folder: SAE USA-US052-2020-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:58:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 17:02:34
User entered '1'	(b) (4), (b) (6)	09 Dec 2020 18:19:26

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
SAEID

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'USA-US052-2020-MRNA-1273-P301000020'	System	01 Dec 2020 16:14:19

FDA-CBER-2022-1614-0193711

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Serious

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Yes (Y)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Death

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Yes (Y)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:35
User closed query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:57:29
Query 'Try changing it again, I think they fixed it' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:07
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:01
User opened query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:20
User closed query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:20
Un-reviewed for Safety.	System	12 Jan 2021 18:25:05
User entered 'Meagan'	System	12 Jan 2021 18:25:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:24:52
Query 'Please change to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:22
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User opened query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:50:19
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Meagan'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:37
User closed query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:57:18
Query 'Try changing it again, I think they fixed it' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:12
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:01
User opened query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:44
User closed query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:44
Un-reviewed for Safety.	System	12 Jan 2021 18:25:05
User entered 'Miller'	System	12 Jan 2021 18:25:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:24:52
Query 'Please change to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:26
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User opened query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:50:39
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Miller'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:44
User closed query 'Please add address, should be current address because SAE occurred after Nov 1 move, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:57:42
Query 'Please add address, should be current address because SAE occurred after Nov 1 move, thanks' answered with 'ADDRESS ADDED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:39
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
User opened query 'Please add address, should be current address because SAE occurred after Nov 1 move, thanks' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:58:47
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:39
User closed query 'Address should be the updated one because this SAE happened after the move. Thanks' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:57:21
Query 'Address should be the updated one because this SAE happened after the move. Thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:19:01
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User opened query 'Address should be the updated one because this SAE happened after the move. Thanks' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:41:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered '330 dakota dunes suite400'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:46
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:41
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'North sioux'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:49
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'IA'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:51
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:46
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered '57049'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 18:19:17
User entered 'US'	System	01 Dec 2020 16:14:48

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 16:37:48
User entered '4'	System	12 Jan 2021 18:25:05
User entered '3'	System	14 Dec 2020 17:02:49
User entered '2'	System	09 Dec 2020 18:19:26
User entered '1'	System	01 Dec 2020 16:14:48

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form (3)
Generated On: 09 Jun 2021 14:58:46
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
User entered '14/Dec/2020 12:02'	System	14 Dec 2020 17:02:49

FDA-CBER-2022-1614-0193727

US3042210

Folder: SAE USA-US052-2020-MRNA-1273-P301000020

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:58:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:24:52
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
User entered '1'	(b) (4), (b) (6)	14 Dec 2020 17:02:49

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
SAEID

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'USA-US052-2020-MRNA-1273-P301000020'	System	01 Dec 2020 16:14:19

FDA-CBER-2022-1614-0193729

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Serious

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Yes (Y)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Death

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Yes (Y)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

FDA-CBER-2022-1614-0193734

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:35
User closed query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:57:29
Query 'Try changing it again, I think they fixed it' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:07
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:01
User opened query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:20
User closed query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:20
Un-reviewed for Safety.	System	12 Jan 2021 18:25:05
User entered 'Meagan'	System	12 Jan 2021 18:25:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:24:52
Query 'Please change to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:22
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User opened query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:50:19
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Meagan'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:37
User closed query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:57:18
Query 'Try changing it again, I think they fixed it' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:12
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:01
User opened query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:44
User closed query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:44
Un-reviewed for Safety.	System	12 Jan 2021 18:25:05
User entered 'Miller'	System	12 Jan 2021 18:25:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:24:52
Query 'Please change to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:26
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User opened query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:50:39
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Miller'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:44
User closed query 'Please add address, should be current address because SAE occurred after Nov 1 move, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:57:42
Query 'Please add address, should be current address because SAE occurred after Nov 1 move, thanks' answered with 'ADDRESS ADDED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:39
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
User opened query 'Please add address, should be current address because SAE occurred after Nov 1 move, thanks' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:58:47
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:39
User closed query 'Address should be the updated one because this SAE happened after the move. Thanks' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:57:21
Query 'Address should be the updated one because this SAE happened after the move. Thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:19:01
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User opened query 'Address should be the updated one because this SAE happened after the move. Thanks' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:41:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered '330 dakota dunes suite400'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:46
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:41
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'North sioux'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:49
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'IA'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:51
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:46
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered '57049'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 18:19:17
User entered 'US'	System	01 Dec 2020 16:14:48

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 16:37:48
User entered '4'	System	12 Jan 2021 18:25:05
User entered '3'	System	14 Dec 2020 17:02:49
User entered '2'	System	09 Dec 2020 18:19:26
User entered '1'	System	01 Dec 2020 16:14:48

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 14:58:46
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:56:12
User entered '12/Jan/2021 13:25'	System	12 Jan 2021 18:25:05

US3042210

Folder: SAE USA-US052-2020-MRNA-1273-P301000020

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:58:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:56:14
User entered '1'	(b) (4), (b) (6)	12 Jan 2021 18:25:05

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
SAEID

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'USA-US052-2020-MRNA-1273-P301000020'	System	01 Dec 2020 16:14:19

FDA-CBER-2022-1614-0193747

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Serious

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Yes (Y)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Death

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Yes (Y)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'No (N)'	System	01 Dec 2020 16:14:19

FDA-CBER-2022-1614-0193754

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:35
User closed query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:57:29
Query 'Try changing it again, I think they fixed it' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:07
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:01
User opened query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:20
User closed query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:20
Un-reviewed for Safety.	System	12 Jan 2021 18:25:05
User entered 'Meagan'	System	12 Jan 2021 18:25:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:24:52
Query 'Please change to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:22
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User opened query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:50:19
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Meagan'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:37
User closed query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:57:18
Query 'Try changing it again, I think they fixed it' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:12
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:01
User opened query 'Try changing it again, I think they fixed it' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:44
User closed query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:40:44
Un-reviewed for Safety.	System	12 Jan 2021 18:25:05
User entered 'Miller'	System	12 Jan 2021 18:25:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:24:52
Query 'Please change to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:26
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 22:42:18
User opened query 'Please change to PI's name' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:50:39
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'Miller'	System	01 Dec 2020 16:14:19

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US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:44
User closed query 'Please add address, should be current address because SAE occurred after Nov 1 move, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:57:42
Query 'Please add address, should be current address because SAE occurred after Nov 1 move, thanks' answered with 'ADDRESS ADDED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:39
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
User opened query 'Please add address, should be current address because SAE occurred after Nov 1 move, thanks' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:58:47
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:39
User closed query 'Address should be the updated one because this SAE happened after the move. Thanks' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:57:21
Query 'Address should be the updated one because this SAE happened after the move. Thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:19:01
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User opened query 'Address should be the updated one because this SAE happened after the move. Thanks' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:41:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered '330 dakota dunes suite400'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:46
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:41
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'North sioux'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:49
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered 'IA'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:51
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:17:19
Un-reviewed for Safety.	System	08 Apr 2021 16:37:48
DataPoint Un-verified.	System	08 Apr 2021 16:37:48
User entered empty.	System	08 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:37:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:45:46
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:18:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:14:38
User entered '57049'	System	01 Dec 2020 16:14:19

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:49:49
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 18:19:17
User entered 'US'	System	01 Dec 2020 16:14:48

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US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form
Generated On: 09 Jun 2021 14:58:46
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 16:37:48
User entered '4'	System	12 Jan 2021 18:25:05
User entered '3'	System	14 Dec 2020 17:02:49
User entered '2'	System	09 Dec 2020 18:19:26
User entered '1'	System	01 Dec 2020 16:14:48

US3042210
Folder: SAE USA-US052-2020-MRNA-1273-P301000020
Form: Safety Report Form (5)
Generated On: 09 Jun 2021 14:58:46
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:48:23
User entered '08/Apr/2021 12:37'	System	08 Apr 2021 16:37:48

FDA-CBER-2022-1614-0193763

US3042210

Folder: SAE USA-US052-2020-MRNA-1273-P301000020

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:58:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:48:23
User entered '1'	(b) (4), (b) (6)	08 Apr 2021 16:37:48