US3432202 (Prod: Brigham and Womens Hospital)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:27:13

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US3432202
Form: Participant Creation
Generated On: 26 Nov 2020 09:27:13

Participant ID	US3432202

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-5927922

US3432202
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

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US3432202
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:27:13

Date of Birth (MMM yyyy)	(b) (6) 1943
Age	77
Age Units	YEARS
Age (Derived)	77
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

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US3432202
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:27:13

Date of Informed Consent *(dd MMM yyyy)*	19 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

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

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US3432202
Folder: Screening
Form: Medical History Summary
Generated On: 26 Nov 2020 09:27:13

Were any significant conditions reported?	Yes ■ No ☐

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US3432202
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:27:13

Condition	DIABETES MELLITUS
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)	

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US3432202
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:27:13

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

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US3432202
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:27:13

Condition	HIGH CHOLESTEROL
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)	

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US3432202
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:27:13

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

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US3432202
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:27:13

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

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US3432202
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:27:13

Condition	CHRONIC FATIGUE (BEING FOLLOWED BY PHYSICIAN)
Start date (dd MMM yyyy)	UN NOV 2019
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)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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US3432202
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:27:13

Condition	NECK PAIN { BEING FOLLOWED BY MD}
Start date (dd MMM yyyy)	UN MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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US3432202
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:27:13

Condition	GAIT INSTABILITY
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)	

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US3432202
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 09:27:13

Condition	CHOREA
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)	

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US3432202
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 09:27:13

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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US3432202
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 09:27:13

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

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US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	19 AUG 2020
Time of assessment *(00:00-23:59)*	14:43 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 14:43
Height *(xxx.x)*	174 cm
Weight *(xxx.x)*	81.7 kg
BMI *(xxx.x)*	26.98507 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)	

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Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	19 AUG 2020

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

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US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13

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	RETIRED
Location and Living Circumstances Risk (check all that apply)	
No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	True
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)	False
Other	False
Specify	

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US3432202
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

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US3432202
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:27:13

What was the date of randomization? *(dd MMM yyyy)*	19 AUG 2020
What was the participant's randomization number?	187067
In what Cohort was the participant enrolled?	>=18 and <65 years and not at risk ☐ >=18 and <65 years and at risk ☐ >=65 years ■

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)	Yes ☐ No ■
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)	Yes ☐ No ■
Severe obesity (body mass index > or = 40kg/m2	Yes ☐ No ■
Diabetes (Type I, Type 2, or gestational)	Yes ■ No ☐
Liver Disease	Yes ☐ No ■
Human Immunodeficiency Virus (HIV) infection	Yes ☐ No ☐

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Height	ND - Not Done
Weight	ND - Not Done

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US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13

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)*	19 AUG 2020
Time of assessment *(00:00-23:59)*	14:43 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 14:43
Temperature *(xxx.x)*	37.2 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	98 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	70 mmHg
Diastolic Blood Pressure units	MMHG

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US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13

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)*	19 AUG 2020
Time of assessment *(00:00-23:59)*	16:09 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 16:09
Temperature *(xxx.x)*	37.4 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	95 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

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US3432202
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 26 Nov 2020 09:27:13

Was the physical examination performed? Yes ☐ No ☒

Date of examination *(dd MMM yyyy)* _____

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

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US3432202
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:27:13

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)*	19 AUG 2020
What was the treatment time? *(00:00-23:59)*	15:39 (24 HR)
Treatment Date and Time (derived)	19 AUG 2020 15:39
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	19 AUG 2020
Collection time *(00:00-23:59)*	14:55 (24 HR)
Collection date and time (derived)	19 AUG 2020 14:55

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Collection date *(dd MMM yyyy)*			19 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:02	19 AUG 2020 15:02
Nasopharyngeal Swab 2	No		

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

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US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:27:13

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**	99.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	19 AUG 2020 16:10
PC Open Date & Time	19 AUG 2020 15:59
PC Close Date & Time	19 AUG 2020 18:29

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US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:27:13

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**	98.7 °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	19 AUG 2020 20:06
PC Open Date & Time	19 AUG 2020 19:24
PC Close Date & Time	20 AUG 2020 11:59

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US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:27:13

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**	99.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	20 AUG 2020 22:02
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

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TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	99.7 °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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	21 AUG 2020 21:08
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.7 °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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	22 AUG 2020 20:08
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

FDA-CBER-2022-1614-5927957

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	23 AUG 2020 19:03
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-5927958

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.9 °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	25 AUG 2020 00:03
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-5927959

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	96.9 °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	25 AUG 2020 22:28
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-5927960

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:27:13

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	19 AUG 2020 16:13
PC Open Date & Time	19 AUG 2020 15:59
PC Close Date & Time	19 AUG 2020 18:29

FDA-CBER-2022-1614-5927961

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:27:13

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	19 AUG 2020 20:07
PC Open Date & Time	19 AUG 2020 19:24
PC Close Date & Time	20 AUG 2020 11:59

FDA-CBER-2022-1614-5927962

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:27:13

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	20 AUG 2020 22:03
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-5927963

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:27:13

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	21 AUG 2020 21:09
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

FDA-CBER-2022-1614-5927964

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:27:13

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	22 AUG 2020 20:08
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

FDA-CBER-2022-1614-5927965

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:27:13

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	23 AUG 2020 19:04
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-5927966

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:27:13

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	25 AUG 2020 00:04
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-5927967

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:27:13

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	25 AUG 2020 22:28
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-5927968

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 ☐

FDA-CBER-2022-1614-5927969

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	19 AUG 2020 16:14
PC Open Date & Time	19 AUG 2020 15:59
PC Close Date & Time	19 AUG 2020 18:29

FDA-CBER-2022-1614-5927970

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 ☐

FDA-CBER-2022-1614-5927971

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	19 AUG 2020 20:09
PC Open Date & Time	19 AUG 2020 19:24
PC Close Date & Time	20 AUG 2020 11:59

FDA-CBER-2022-1614-5927972

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13

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 ☐

FDA-CBER-2022-1614-5927973

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13

	Yes
PC Time stamp	20 AUG 2020 22:05
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-5927974

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 3
HEADACHE	None ☐
	No interference with activity ■
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ☐
	No interference with activity ■
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐

FDA-CBER-2022-1614-5927975

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5927976

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13

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-2022-1614-5927977

	Yes ☐
PC Time stamp	22 AUG 2020 20:10
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13

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-2022-1614-5927979

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13

	Yes ☐
PC Time stamp	23 AUG 2020 19:05
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-5927980

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:27:13

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-2022-1614-5927981

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:27:13

	Yes ☐
PC Time stamp	25 AUG 2020 00:05
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-5927982

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5927983

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13

	Yes ☐
PC Time stamp	25 AUG 2020 22:29
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-5927984

US3432202
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **HEADACHE**	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interfererence with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	26 AUG 2020 22:14
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-5927985

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	26 AUG 2020 22:14
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-5927986

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 9
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	27 AUG 2020 12:01
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

FDA-CBER-2022-1614-5927987

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(10)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 10
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ☐ Some interference with activity ■ Significant; prevents daily activity ☐
PC Time Stamp	28 AUG 2020 21:12
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-5927988

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(11)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 11
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	29 AUG 2020 12:57
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-5927989

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(12)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 12
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	30 AUG 2020 19:53
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

FDA-CBER-2022-1614-5927990

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(13)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 13
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	31 AUG 2020 15:40
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

FDA-CBER-2022-1614-5927991

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(14)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 14
Select one response below to indicate the intensity of your **FATIGUE**	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	01 SEP 2020 12:26
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

FDA-CBER-2022-1614-5927992

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	26 AUG 2020 22:14
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-5927993

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 9
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	27 AUG 2020 12:01
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

FDA-CBER-2022-1614-5927994

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 10
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	28 AUG 2020 21:12
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-5927995

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 11
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	29 AUG 2020 12:57
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-5927996

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 12
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	30 AUG 2020 19:53
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

FDA-CBER-2022-1614-5927997

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	31 AUG 2020 15:40
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

FDA-CBER-2022-1614-5927998

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 14
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	01 SEP 2020 12:26
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

FDA-CBER-2022-1614-5927999

US3432202
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	26 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-2022-1614-5928000

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

FDA-CBER-2022-1614-5928001

US3432202
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	02 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-2022-1614-5928002

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

FDA-CBER-2022-1614-5928003

US3432202
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	09 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-2022-1614-5928004

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

FDA-CBER-2022-1614-5928005

US3432202
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-5928006

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	16 SEP 2020
Time of assessment *(00:00-23:59)*	13:55 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 13:55
Temperature *(xxx.x)*	37.1 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	95 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	061 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-5928007

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	16 SEP 2020
Time of assessment *(00:00-23:59)*	16:00 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 16:00
Temperature *(xxx.x)*	97.1 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	IR
Pulse *(xxx)*	096 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	067 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-5928008

US3432202
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 09:27:13

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	16 SEP 2020

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

FDA-CBER-2022-1614-5928009

US3432202
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:27:13

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)*	16 SEP 2020
What was the treatment time? *(00:00-23:59)*	15:24 (24 HR)
Treatment Date and Time (derived)	16 SEP 2020 15:24
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-2022-1614-5928010

US3432202
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:27:13

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	16 SEP 2020
Collection time *(00:00-23:59)*	14:20 (24 HR)
Collection date and time (derived)	16 SEP 2020 14:20

FDA-CBER-2022-1614-5928011

Collection date *(dd MMM yyyy)*			16 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:22	16 SEP 2020 14:22
Nasopharyngeal Swab 2	No		

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

FDA-CBER-2022-1614-5928013

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:27:13

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**	97.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	16 SEP 2020 16:09
PC Open Date & Time	16 SEP 2020 15:44
PC Close Date & Time	16 SEP 2020 18:14

FDA-CBER-2022-1614-5928014

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	99.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	16 SEP 2020 21:48
PC Open Date & Time	16 SEP 2020 19:09
PC Close Date & Time	17 SEP 2020 11:59

FDA-CBER-2022-1614-5928015

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:27:13

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**	98.6 °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	17 SEP 2020 12:02
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

FDA-CBER-2022-1614-5928016

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.6 °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 SEP 2020 00:08
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-5928017

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.0 °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	19 SEP 2020 22:39
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

FDA-CBER-2022-1614-5928018

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:27:13

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**	97.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	20 SEP 2020 22:11
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

FDA-CBER-2022-1614-5928019

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**	
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	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-5928020

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:27:13

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**	97.5 °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	22 SEP 2020 16:20
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-5928021

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:27:13

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	16 SEP 2020 16:10
PC Open Date & Time	16 SEP 2020 15:44
PC Close Date & Time	16 SEP 2020 18:14

FDA-CBER-2022-1614-5928022

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	16 SEP 2020 21:48
PC Open Date & Time	16 SEP 2020 19:09
PC Close Date & Time	17 SEP 2020 11:59

FDA-CBER-2022-1614-5928023

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:27:13

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	17 SEP 2020 12:03
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

FDA-CBER-2022-1614-5928024

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:27:13

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 SEP 2020 00:09
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-5928025

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:27:13

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	19 SEP 2020 22:40
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

FDA-CBER-2022-1614-5928026

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928027

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 ☐
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	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-5928028

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:27:13

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	22 SEP 2020 19:55
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-5928029

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 ☐

FDA-CBER-2022-1614-5928030

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☑ Yes ☐
PC Time stamp	16 SEP 2020 16:11
PC Open Date & Time	16 SEP 2020 15:44
PC Close Date & Time	16 SEP 2020 18:14

FDA-CBER-2022-1614-5928031

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 ☐

FDA-CBER-2022-1614-5928032

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☑ Yes ☐
PC Time stamp	16 SEP 2020 21:49
PC Open Date & Time	16 SEP 2020 19:09
PC Close Date & Time	17 SEP 2020 11:59

FDA-CBER-2022-1614-5928033

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13

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 ■

FDA-CBER-2022-1614-5928034

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13

	Yes ☐
PC Time stamp	17 SEP 2020 12:03
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

FDA-CBER-2022-1614-5928035

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 3
HEADACHE	None ■
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-5928036

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13

	Yes ☐
PC Time stamp	19 SEP 2020 00:10
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-5928037

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13

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-2022-1614-5928038

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13

	Yes ☐
PC Time stamp	19 SEP 2020 22:41
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

FDA-CBER-2022-1614-5928039

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13

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-2022-1614-5928040

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13

	Yes ☐
PC Time stamp	20 SEP 2020 22:13
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

FDA-CBER-2022-1614-5928041

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:27:13

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-2022-1614-5928042

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

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928044

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13

	Yes ☐
PC Time stamp	22 SEP 2020 19:56
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-5928045

US3432202
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	26 SEP 2020
Please select one status for the follow-up contact	Contact Made ☐ Contact Not Made ■
Comments *If Contact Not Made, please provide Comments*	CALLED PT. 9/25/2020 AT 6:30PM, 9/26/2020 AT 11:59AM AND 2:51PM. ALSO EMAILED PARTICIPANT ON 9/26/2020.

FDA-CBER-2022-1614-5928046

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

FDA-CBER-2022-1614-5928047

US3432202
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	2 OCT 2020
Please select one status for the follow-up contact	Contact Made ☐ Contact Not Made ■
Comments *If Contact Not Made, please provide Comments*	PT. CALLED ON 29SEP2020 AT 10:22AM, 30SEP2020 AT 6:34PM, AND 01OCT2020 AT 10:55AM AND 4:35PM. PT ALSO EMAILED ON 01OCT2020 AND NO CONTACT WAS MADE.

FDA-CBER-2022-1614-5928048

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

FDA-CBER-2022-1614-5928049

US3432202
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	8 OCT 2020
Please select one status for the follow-up contact	Contact Made ☐ Contact Not Made ■
Comments *If Contact Not Made, please provide Comments*	PARTICIPANT CALLED 9:06 AND 13:48 ON 06OCT2020, 10:30 AND 17:39 ON 07OCT2020, AND 9:44 08OCT2020

FDA-CBER-2022-1614-5928050

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

FDA-CBER-2022-1614-5928051

US3432202
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	2 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-5928052

US3432202
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	2 NOV 2020
Time of assessment *(00:00-23:59)*	13:40 (24 HR)
Vital Signs Date and Time (derived)	2 NOV 2020 13:40
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	097 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	015 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	068 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-5928053

US3432202
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 09:27:13

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-2022-1614-5928054

US3432202
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:27:13

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	2 NOV 2020
Collection time *(00:00-23:59)*	13:50 (24 HR)
Collection date and time (derived)	2 NOV 2020 13:50

FDA-CBER-2022-1614-5928055

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

FDA-CBER-2022-1614-5928056

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Date and time of submission	21 OCT 2020 09:11:34
Patient Cloud Open Date & Time	19 OCT 2020 00:01
Patient Cloud Close Date & Time	23 OCT 2020 23:59

FDA-CBER-2022-1614-5928057

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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	28 OCT 2020 12:16:59
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

FDA-CBER-2022-1614-5928058

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Date and time of submission	04 NOV 2020 11:56:04
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

FDA-CBER-2022-1614-5928059

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Date and time of submission	16 NOV 2020 15:17:29
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

FDA-CBER-2022-1614-5928060

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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	16 OCT 2020 00:01
Patient Cloud Close Date & Time	20 OCT 2020 23:59

FDA-CBER-2022-1614-5928062

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928064

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928066

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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	06 NOV 2020 00:01
Patient Cloud Close Date & Time	10 NOV 2020 23:59

FDA-CBER-2022-1614-5928068

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 NOV 2020 00:01
Patient Cloud Close Date & Time	17 NOV 2020 23:59

FDA-CBER-2022-1614-5928070

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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 12:24:55
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

FDA-CBER-2022-1614-5928071

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

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928073

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

FDA-CBER-2022-1614-5928075

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 ☐

FDA-CBER-2022-1614-5928076

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

FDA-CBER-2022-1614-5928077

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

FDA-CBER-2022-1614-5928078

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

FDA-CBER-2022-1614-5928079

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

FDA-CBER-2022-1614-5928081

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928083

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928085

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 ☐

FDA-CBER-2022-1614-5928086

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928087

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 ☐

FDA-CBER-2022-1614-5928088

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928089

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

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928091

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

FDA-CBER-2022-1614-5928093

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

FDA-CBER-2022-1614-5928095

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

FDA-CBER-2022-1614-5928097

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

FDA-CBER-2022-1614-5928098

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928099

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928101

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

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928103

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

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928105

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928107

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

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928109

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928111

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 ☐

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

FDA-CBER-2022-1614-5928113

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 ☐

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

FDA-CBER-2022-1614-5928115

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928117

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928119

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928121

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928123

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 ☐

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

FDA-CBER-2022-1614-5928125

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928127

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928129

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928131

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928133

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928135

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 ☐

FDA-CBER-2022-1614-5928136

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928137

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 ☐

FDA-CBER-2022-1614-5928138

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928139

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928141

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928143

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928145

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 ☐

FDA-CBER-2022-1614-5928146

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

FDA-CBER-2022-1614-5928147

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928149

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 ☐

FDA-CBER-2022-1614-5928150

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928151

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928153

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928155

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 ☐

FDA-CBER-2022-1614-5928156

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

FDA-CBER-2022-1614-5928157

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 ☐

FDA-CBER-2022-1614-5928158

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928159

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 ☐

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

FDA-CBER-2022-1614-5928161

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928163

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928165

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 ☐

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

FDA-CBER-2022-1614-5928167

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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 ☐

FDA-CBER-2022-1614-5928168

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928169

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928171

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 ☐

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

FDA-CBER-2022-1614-5928173

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 ☐

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

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 ☐

FDA-CBER-2022-1614-5928176

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928177

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928179

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928181

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 ☐

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

FDA-CBER-2022-1614-5928183

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928185

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 ☐

FDA-CBER-2022-1614-5928186

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	31 DEC 2021 00:01
Patient Cloud Close Date & Time	04 JAN 2022 23:59

FDA-CBER-2022-1614-5928187

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 ☐

FDA-CBER-2022-1614-5928188

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928189

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928191

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 ☐

FDA-CBER-2022-1614-5928192

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

FDA-CBER-2022-1614-5928193

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928195

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 ☐

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

FDA-CBER-2022-1614-5928197

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928199

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928201

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 ☐

FDA-CBER-2022-1614-5928202

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928203

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 ☐

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

FDA-CBER-2022-1614-5928205

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 ☐

FDA-CBER-2022-1614-5928206

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928207

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928209

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928211

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 ☐

FDA-CBER-2022-1614-5928212

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928213

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928215

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 ☐

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

FDA-CBER-2022-1614-5928217

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 ☐

FDA-CBER-2022-1614-5928218

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

FDA-CBER-2022-1614-5928219

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 ☐

FDA-CBER-2022-1614-5928220

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928221

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 ☐

FDA-CBER-2022-1614-5928222

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928223

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 ☐

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

FDA-CBER-2022-1614-5928225

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 ☐

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

FDA-CBER-2022-1614-5928227

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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 ☐

FDA-CBER-2022-1614-5928228

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

FDA-CBER-2022-1614-5928229

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 ☐

FDA-CBER-2022-1614-5928230

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928231

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 ☐

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

FDA-CBER-2022-1614-5928233

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 ☐

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

FDA-CBER-2022-1614-5928235

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 ☐

FDA-CBER-2022-1614-5928236

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928237

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928239

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928241

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-5928242

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928243

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928245

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 ☐

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	29 JUL 2022 00:01
Patient Cloud Close Date & Time	02 AUG 2022 23:59

FDA-CBER-2022-1614-5928247

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 ☐

FDA-CBER-2022-1614-5928248

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928249

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 ☐

FDA-CBER-2022-1614-5928250

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928251

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 ☐

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

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

FDA-CBER-2022-1614-5928255

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 ☐

FDA-CBER-2022-1614-5928256

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928257

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 ☐

FDA-CBER-2022-1614-5928258

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928259

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 ☐

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

FDA-CBER-2022-1614-5928261

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 ☐

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

FDA-CBER-2022-1614-5928263

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 ☐

FDA-CBER-2022-1614-5928264

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928265

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-5928266

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928267

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 ☐

FDA-CBER-2022-1614-5928268

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928269

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 ☐

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

US3432202
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	12 NOV 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-2022-1614-5928272

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

FDA-CBER-2022-1614-5928273

US3432202
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13

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	

FDA-CBER-2022-1614-5928274

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

FDA-CBER-2022-1614-5928275

US3432202
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 26 Nov 2020 09:27:13

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-2022-1614-5928276

Generate Next COVID-19 Assessment	Yes ☐ No ☐

FDA-CBER-2022-1614-5928277

US3432202
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 26 Nov 2020 09:27:13

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

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-5928278

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13

AEID	
Adverse event	FOREIGN BODY IN FOOT
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)*	20 AUG 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	2 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

FDA-CBER-2022-1614-5928279

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

FDA-CBER-2022-1614-5928280

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13

AEID	USA-US078-2020-MRNA-1273-P301000003
Adverse event	HYPERTENSIVE URGENCY
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)*	25 SEP 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	30 SEP 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)*	25 SEP 2020
Hospital Discharge Date *(dd MMM yyyy)*	30 SEP 2020
Admitted to ICU?	Yes ☐ No ■ Unknown ☐
Number of Days in ICU	

FDA-CBER-2022-1614-5928281

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

FDA-CBER-2022-1614-5928282

PT RECEIVED SECOND VACCINE 16SEP2020. PATIENT WAS FOUND THIS MORNING WALKING OUTSIDE DISORIENTED BY A BYSTANDER WHO CALLED EMS. ALSO REPORTS DIZZINESS. WAS ADMITTED TODAY BECAUSE OF THE CONFUSION. HAD A CEREBRAL SCAN WITHOUT SIGNIFICANT CHANGES FROM PREVIOUS SCAN DONE IN 2019. HAD HTN IN THE ED (UP TO 204 SYSTOLIC) HE IS KNOWN WITH HTN, WHICH IS CAPTURED IN THE MEDICAL HISTORY.
02 OCT 2020- SAE DISCHARGE UPDATE: PT WAS HOSPITALIZED FROM 9/25 TO 9/30 FOR CONFUSION IN THE CONTEXT OF UNCONTROLLED HYPERTENSION. BP WAS CONTROLLED DURING HOSPITALIZATION WITH LISINOPRIL 5MG QD WHICH MUCH IMPROVEMENT. PT WAS BACK TO BASELINE AT DISCHARGE.
30OCT2020 UPDATED: HEAD CT (25SEP2020), CHEST XR (25SEP2020), BRAIN MRI (25SEP2020), CERVICAL SPINE MRI (28SEP2020) - ALL IMAGING SHOWED NO ACUTE FINDING THAT CAN EXPLAIN CONFUSION. EEG (29SEP2020) -

FDA-CBER-2022-1614-5928283

	NO EPILEPTIFORM OR LATERALIZING ABNORMALITIES LP (26SEP2020) - WBC COUNT OF 1, HSV PCR NEGATIVE, VIRAL CULTURE NEGATIVE, BACTERIA CULTURE NEGATIVE
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

FDA-CBER-2022-1614-5928284

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13

AEID	
Adverse event	DIZZINESS
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)*	02 OCT 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ■ No ☐
If not Ongoing, end date *(dd MMM yyyy)*	
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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ■ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

FDA-CBER-2022-1614-5928286

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 26 Nov 2020 09:27:13

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

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

FDA-CBER-2022-1614-5928287

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	GLYBURIDE
Prophylaxis	Yes ☐ No ■
Indication	DIABETES MELLITUS
Dose per administration	UNK
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	UNKNOWN
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 ☐

FDA-CBER-2022-1614-5928288

	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)*	
Start date completely unknown	True
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
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 ☐

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13

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

FDA-CBER-2022-1614-5928290

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

FDA-CBER-2022-1614-5928291

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	GLIPIZIDE
Prophylaxis	Yes ☐
	No ■
Indication	DIABETES MELLITUS
Dose per administration	UNK
Dose unit	mg ☐
	ug ☐
	mL ☐
	g ☐
	IU ☐
	tablet ☐
	capsule ☐
	puff ☐
	Other ■
If dose unit is Other, specify	UNKNOWN
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 ☐

FDA-CBER-2022-1614-5928292

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

FDA-CBER-2022-1614-5928293

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	PROZAC
Prophylaxis	Yes ☐ No ■
Indication	ANXIETY
Dose per administration	UNK
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	UNKNOWN
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 ☐

FDA-CBER-2022-1614-5928294

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

FDA-CBER-2022-1614-5928295

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	SIMVASTATIN
Prophylaxis	Yes ☐ No ■
Indication	HIGH CHOLESTEROL
Dose per administration	UNK
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	UNKNOWN
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 ☐

FDA-CBER-2022-1614-5928296

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

FDA-CBER-2022-1614-5928297

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	PANTOPRAZOLE
Prophylaxis	Yes ☐
	No ■
Indication	DUODENAL ULCER
Dose per administration	UNK
Dose unit	mg ☐
	ug ☐
	mL ☐
	g ☐
	IU ☐
	tablet ☐
	capsule ☐
	puff ☐
	Other ■
If dose unit is Other, specify	UNKNOWN
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 ☐

FDA-CBER-2022-1614-5928298

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

FDA-CBER-2022-1614-5928299

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	NSAIDS
Prophylaxis	Yes ☐ No ■
Indication	HEADACHE
Dose per administration	UNK
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	UNKNOWN
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 ☐

FDA-CBER-2022-1614-5928300

	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)*	
Start date completely unknown	True
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
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 ☐

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ■
Indication	FOREIGN BODY IN FOOT
Dose per administration	200
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

FDA-CBER-2022-1614-5928302

	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	21 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	1 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 ☐

FDA-CBER-2022-1614-5928303

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	AMLODIPINE
Prophylaxis	Yes ☐ No ■
Indication	HTN
Dose per administration	5
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

FDA-CBER-2022-1614-5928304

	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 JAN 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	25 SEP 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	LISINOPRIL
Prophylaxis	Yes ☐ No ■
Indication	HTN
Dose per administration	5
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

FDA-CBER-2022-1614-5928306

	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)*	27 SEP 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 ■

FDA-CBER-2022-1614-5928307

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	LABETALOL
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
Dose per administration	200
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

FDA-CBER-2022-1614-5928308

	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)*	25 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	25 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 ☐

FDA-CBER-2022-1614-5928309

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	LABETALOL
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
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	TWICE
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

FDA-CBER-2022-1614-5928310

	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)*	25 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	25 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 ☐

FDA-CBER-2022-1614-5928311

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	LABETALOL
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
Dose per administration	20
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

FDA-CBER-2022-1614-5928312

	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)*	25 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	25 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 ☐

FDA-CBER-2022-1614-5928313

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	HYDRALAZINE
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
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 ☐

FDA-CBER-2022-1614-5928314

	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)*	25 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	25 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 ☐

FDA-CBER-2022-1614-5928315

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ■
Indication	MILD PAIN IN HOSPITAL
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 ☐

FDA-CBER-2022-1614-5928316

	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)*	25 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	25 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 ☐

FDA-CBER-2022-1614-5928317

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	LISINOPRIL
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
Dose per administration	2.5
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

FDA-CBER-2022-1614-5928318

	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	30 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	30 SEP 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

FDA-CBER-2022-1614-5928319

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ■
Indication	MILD PAIN WHILE IN HOSPITAL
Dose per administration	400
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

FDA-CBER-2022-1614-5928320

	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)*	28 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	30 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 ☐

FDA-CBER-2022-1614-5928321

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	SENOKOT
Prophylaxis	Yes ☐ No ■
Indication	MILD CONSTIPATION
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ■ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ■ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

FDA-CBER-2022-1614-5928322

	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)*	26 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	30 SEP 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

FDA-CBER-2022-1614-5928323

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	LOVENOX
Prophylaxis	Yes ■ No ☐
Indication	BLOOD CLOT PREVENTION
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 ☐

FDA-CBER-2022-1614-5928324

	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)*	28 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	30 SEP 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

FDA-CBER-2022-1614-5928325

Name of Medication	METFORMIN
Prophylaxis	Yes ☐ No ■
Indication	DM
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)*	
Start date completely unknown	True
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

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US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	TRAZODONE
Prophylaxis	Yes ☐ No ■
Indication	ANXIETY AND DEPRESSION
Dose per administration	100
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

FDA-CBER-2022-1614-5928328

	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)*	
Start date completely unknown	True
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 ■

FDA-CBER-2022-1614-5928329

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	MIRTAZAPINE
Prophylaxis	Yes ☐ No ■
Indication	DEPRESSION
Dose per administration	30
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

FDA-CBER-2022-1614-5928330

	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)*	
Start date completely unknown	True
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 ■

FDA-CBER-2022-1614-5928331

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ■
Indication	UNKNOWN
Dose per administration	200
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ■
If frequency is Other, specify	8X DAILY
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

FDA-CBER-2022-1614-5928332

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

FDA-CBER-2022-1614-5928333

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 26 Nov 2020 09:27:13

Were any concomitant procedures performed?	Yes ■ No ☐

If yes, please complete Concomitant Procedures form.

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US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures
Generated On: 26 Nov 2020 09:27:13

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
20 AUG 2020	FOREIGN BODY REMOVAL FROM FOOT	Adverse Event	
25 SEP 2020	CT HEAD AND NECK	Adverse Event	
25 SEP 2020	MRI BRAIN	Adverse Event	
28 SEP 2020	MRI NECK	Adverse Event	
25 SEP 2020	CHEST X-RAY	Adverse Event	
25 SEP 2020	ECG	Adverse Event	
29 SEP 2020	EEG	Adverse Event	

US3432202
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 26 Nov 2020 09:27:13

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-2022-1614-5928336

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-2022-1614-5928337

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13

SAEID	USA-US078-2020-MRNA-1273-P301000003
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

FDA-CBER-2022-1614-5928338

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form (1)
Generated On: 26 Nov 2020 09:27:13

SAEID	USA-US078-2020-MRNA-1273-P301000003
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	28/SEP/2020 08:53
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

FDA-CBER-2022-1614-5928339

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form (2)
Generated On: 26 Nov 2020 09:27:13

SAEID	USA-US078-2020-MRNA-1273-P301000003
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	05/OCT/2020 09:29
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

FDA-CBER-2022-1614-5928340

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form (3)
Generated On: 26 Nov 2020 09:27:13

SAEID	USA-US078-2020-MRNA-1273-P301000003
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/OCT/2020 16:18
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

FDA-CBER-2022-1614-5928341

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form (4)
Generated On: 26 Nov 2020 09:27:13

SAEID	USA-US078-2020-MRNA-1273-P301000003
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	30/OCT/2020 15:34
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

FDA-CBER-2022-1614-5928342

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form (5)
Generated On: 26 Nov 2020 09:27:13

SAEID	USA-US078-2020-MRNA-1273-P301000003
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	11/NOV/2020 16:47
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

FDA-CBER-2022-1614-5928343

Audit

US3432202 (Prod: Brigham and Womens Hospital)

US3432202
Form: Participant Creation
Generated On: 26 Nov 2020 09:27:13
Participant ID

Audit	User	Time (GMT)
User entered 'US3432202'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:04:31

FDA-CBER-2022-1614-5928345

US3432202
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13
Was this visit performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 18:42:07

FDA-CBER-2022-1614-5928346

US3432202
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:04:33

FDA-CBER-2022-1614-5928347

US3432202
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 18:42:07

FDA-CBER-2022-1614-5928348

US3432202
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13
Folder OID

Audit	User	Time (GMT)
User entered 'SCRN'	System	19 Aug 2020 18:42:07

FDA-CBER-2022-1614-5928349

US3432202
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:27:13
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1943'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:04:34

FDA-CBER-2022-1614-5928350

US3432202
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:27:13
Age

Audit	User	Time (GMT)
User entered '77'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:41:32

FDA-CBER-2022-1614-5928351

US3432202
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:27:13
Age Units

Audit	User	Time (GMT)
User entered 'YEARS'	System	19 Aug 2020 20:41:32

FDA-CBER-2022-1614-5928352

US3432202
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:27:13
Age (Derived)

Audit	User	Time (GMT)
User entered '77'	System	19 Aug 2020 18:42:25

FDA-CBER-2022-1614-5928353

US3432202
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:27:13
Sex

Audit	User	Time (GMT)
User entered 'Male (M)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:41:32

FDA-CBER-2022-1614-5928354

US3432202
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:27:13
Ethnicity

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:41:32

FDA-CBER-2022-1614-5928355

US3432202
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:27:13
White

Audit	User	Time (GMT)
User entered '1'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:41:32

FDA-CBER-2022-1614-5928356

US3432202
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:27:13
Black

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:41:32

FDA-CBER-2022-1614-5928357

US3432202
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:27:13
Asian

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:41:32

FDA-CBER-2022-1614-5928358

US3432202
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:27:13
American Indian or Alaska Native

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:41:32

FDA-CBER-2022-1614-5928359

US3432202
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:27:13
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:41:32

FDA-CBER-2022-1614-5928360

US3432202
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:27:13
Other

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:41:32

FDA-CBER-2022-1614-5928361

US3432202
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:27:13
If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:41:32

FDA-CBER-2022-1614-5928362

US3432202
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:27:13
Unknown

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:41:32

FDA-CBER-2022-1614-5928363

US3432202
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:27:13
Not reported

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:41:32

FDA-CBER-2022-1614-5928364

US3432202
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:27:13
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 18:42:25

FDA-CBER-2022-1614-5928365

US3432202
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:27:13
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	19 Aug 2020 18:42:25

FDA-CBER-2022-1614-5928366

US3432202
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:27:13
Year of Informed Consent (derived)

Audit	User	Time (GMT)
User entered '2020'	System	19 Aug 2020 18:42:25

FDA-CBER-2022-1614-5928367

US3432202
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:27:13
Protocol Version

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 18:42:25

FDA-CBER-2022-1614-5928368

US3432202
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:27:13
Was participant enrolled in the study?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 18:42:25

FDA-CBER-2022-1614-5928369

US3432202
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:27:13
If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 18:42:25

FDA-CBER-2022-1614-5928370

US3432202
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:27:13
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 18:42:25

FDA-CBER-2022-1614-5928371

US3432202
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:27:13
Was this participant screened previously?

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 18:42:25

FDA-CBER-2022-1614-5928372

US3432202
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:27:13
If Yes, previous participant number

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:04:33

FDA-CBER-2022-1614-5928373

US3432202
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:27:13
Enrollment Trigger

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:42:29

FDA-CBER-2022-1614-5928374

US3432202
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 26 Nov 2020 09:27:13
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 18:42:29

FDA-CBER-2022-1614-5928375

US3432202
Folder: Screening
Form: Medical History Summary
Generated On: 26 Nov 2020 09:27:13
Were any significant conditions reported?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:41:39

FDA-CBER-2022-1614-5928376

US3432202
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:27:13
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 20:46:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 20:46:19
Data point term sent to Coder	System	19 Aug 2020 20:45:03
User entered 'Diabetes mellitus'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:44:58

FDA-CBER-2022-1614-5928377

US3432202
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:27:13
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:44:58

FDA-CBER-2022-1614-5928378

US3432202
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:44:58

FDA-CBER-2022-1614-5928379

US3432202
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:27:13
Condition ongoing at study entry

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 20:45:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 20:45:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:45:08
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 20:44:58
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:44:58

FDA-CBER-2022-1614-5928380

US3432202
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:27:13
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:44:58

FDA-CBER-2022-1614-5928381

US3432202
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:27:13
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:44:58

FDA-CBER-2022-1614-5928382

US3432202
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:27:13
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	19 Aug 2020 20:44:58

FDA-CBER-2022-1614-5928383

US3432202
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:27:13
Start Year (derived)

Audit	User	Time (GMT)
User entered '2010'	System	19 Aug 2020 20:44:58

FDA-CBER-2022-1614-5928384

US3432202
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:27:13
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 20:44:58

FDA-CBER-2022-1614-5928385

US3432202
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:27:13
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 20:44:58

FDA-CBER-2022-1614-5928386

US3432202
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:27:13
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 20:48:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 20:48:07
Data point term sent to Coder	System	19 Aug 2020 20:47:09
User entered 'Anxiety'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:46:30

FDA-CBER-2022-1614-5928387

US3432202
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:27:13
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un UNK 2005'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:46:30

FDA-CBER-2022-1614-5928388

US3432202
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:46:30

FDA-CBER-2022-1614-5928389

US3432202
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:27:13
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:46:30

FDA-CBER-2022-1614-5928390

US3432202
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:27:13
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:46:30

FDA-CBER-2022-1614-5928391

US3432202
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:27:13
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:46:30

FDA-CBER-2022-1614-5928392

US3432202
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:27:13
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	19 Aug 2020 20:46:30

FDA-CBER-2022-1614-5928393

US3432202
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:27:13
Start Year (derived)

Audit	User	Time (GMT)
User entered '2005'	System	19 Aug 2020 20:46:30

FDA-CBER-2022-1614-5928394

US3432202
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:27:13
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 20:46:30

FDA-CBER-2022-1614-5928395

US3432202
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:27:13
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 20:46:30

FDA-CBER-2022-1614-5928396

US3432202
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:27:13
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 20:48:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 20:48:07
Data point term sent to Coder	System	19 Aug 2020 20:47:08
User entered 'High cholesterol'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:46:48

FDA-CBER-2022-1614-5928397

US3432202
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:27:13
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:46:48

FDA-CBER-2022-1614-5928398

US3432202
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:46:48

FDA-CBER-2022-1614-5928399

US3432202
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:27:13
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:46:48

FDA-CBER-2022-1614-5928400

US3432202
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:27:13
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:46:48

FDA-CBER-2022-1614-5928401

US3432202
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:27:13
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:46:48

FDA-CBER-2022-1614-5928402

US3432202
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:27:13
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	19 Aug 2020 20:46:48

FDA-CBER-2022-1614-5928403

US3432202
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:27:13
Start Year (derived)

Audit	User	Time (GMT)
User entered '2010'	System	19 Aug 2020 20:46:48

FDA-CBER-2022-1614-5928404

US3432202
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:27:13
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 20:46:48

FDA-CBER-2022-1614-5928405

US3432202
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:27:13
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 20:46:48

FDA-CBER-2022-1614-5928406

US3432202
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:27:13
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Duodenal ulcers and perforation, PT: Duodenal ulcer, LLT: Duodenal ulcer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 20:48:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 20:48:07
Data point term sent to Coder	System	19 Aug 2020 20:47:09
User entered 'Duodenal ulcer'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:47:04

US3432202
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:27:13
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:47:04

FDA-CBER-2022-1614-5928408

US3432202
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:47:04

FDA-CBER-2022-1614-5928409

US3432202
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:27:13
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:47:04

FDA-CBER-2022-1614-5928410

US3432202
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:27:13
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:47:04

FDA-CBER-2022-1614-5928411

US3432202
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:27:13
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:47:04

FDA-CBER-2022-1614-5928412

US3432202
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:27:13
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	19 Aug 2020 20:47:04

FDA-CBER-2022-1614-5928413

US3432202
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:27:13
Start Year (derived)

Audit	User	Time (GMT)
User entered '2019'	System	19 Aug 2020 20:47:04

FDA-CBER-2022-1614-5928414

US3432202
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:27:13
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 20:47:04

FDA-CBER-2022-1614-5928415

US3432202
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:27:13
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 20:47:04

FDA-CBER-2022-1614-5928416

US3432202
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:27:13
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 12:20:35
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 12:20:35
Data point term sent to Coder	System	19 Oct 2020 18:49:25
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 18:49:03
User entered 'Daily HEADACHES' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 18:49:03
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 20:50:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 20:50:06
Data point term sent to Coder	System	19 Aug 2020 20:49:11
User entered 'occasional headaches'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:48:47

FDA-CBER-2022-1614-5928417

US3432202
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:27:13
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:48:47

FDA-CBER-2022-1614-5928418

US3432202
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:48:47

FDA-CBER-2022-1614-5928419

US3432202
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:27:13
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:48:47

FDA-CBER-2022-1614-5928420

US3432202
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:27:13
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:48:47

FDA-CBER-2022-1614-5928421

US3432202
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:27:13
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:48:47

FDA-CBER-2022-1614-5928422

US3432202
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:27:13
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	19 Aug 2020 20:48:47

FDA-CBER-2022-1614-5928423

US3432202
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:27:13
Start Year (derived)

Audit	User	Time (GMT)
User entered '2019'	System	19 Aug 2020 20:48:47

FDA-CBER-2022-1614-5928424

US3432202
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:27:13
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 20:48:47

FDA-CBER-2022-1614-5928425

US3432202
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:27:13
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 20:48:47

FDA-CBER-2022-1614-5928426

US3432202
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:27:13
Condition

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Chronic fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 06:15:45
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 06:15:45
Data point term sent to Coder	System	02 Sep 2020 00:25:31
User entered 'chronic fatigue (being followed by physician)'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:24:42

FDA-CBER-2022-1614-5928427

US3432202
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:27:13
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN Nov 2019'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:24:42

FDA-CBER-2022-1614-5928428

US3432202
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:24:42

FDA-CBER-2022-1614-5928429

US3432202
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:27:13
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:24:42

FDA-CBER-2022-1614-5928430

US3432202
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:27:13
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:24:42

FDA-CBER-2022-1614-5928431

US3432202
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:27:13
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:24:42

FDA-CBER-2022-1614-5928432

US3432202
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:27:13
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Nov 2019'	System	02 Sep 2020 00:24:42

FDA-CBER-2022-1614-5928433

US3432202
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:27:13
Start Year (derived)

Audit	User	Time (GMT)
User entered '2019'	System	02 Sep 2020 00:24:42

FDA-CBER-2022-1614-5928434

US3432202
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:27:13
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 00:24:42

FDA-CBER-2022-1614-5928435

US3432202
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:27:13
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 00:24:42

FDA-CBER-2022-1614-5928436

US3432202
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:27:13
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 05:52:53
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 05:52:53
Data point term sent to Coder	System	16 Sep 2020 21:52:24
User entered 'Neck pain { being followed by MD}'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:52:07

FDA-CBER-2022-1614-5928437

US3432202
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:27:13
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN May 2020'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:52:07

FDA-CBER-2022-1614-5928438

US3432202
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:52:07

FDA-CBER-2022-1614-5928439

US3432202
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:27:13
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:52:07

FDA-CBER-2022-1614-5928440

US3432202
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:27:13
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:52:07

FDA-CBER-2022-1614-5928441

US3432202
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:27:13
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:52:07

FDA-CBER-2022-1614-5928442

US3432202
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:27:13
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'May 2020'	System	16 Sep 2020 21:52:07

FDA-CBER-2022-1614-5928443

US3432202
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:27:13
Start Year (derived)

Audit	User	Time (GMT)
User entered '2020'	System	16 Sep 2020 21:52:07

FDA-CBER-2022-1614-5928444

US3432202
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:27:13
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:52:07

FDA-CBER-2022-1614-5928445

US3432202
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:27:13
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:52:07

FDA-CBER-2022-1614-5928446

US3432202
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:27:13
Condition

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Gait disturbances, PT: Gait disturbance, LLT: Gait instability - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:54:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:54:43
Data point term sent to Coder	System	16 Sep 2020 21:53:26
User entered 'gait instability'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:52:41

FDA-CBER-2022-1614-5928447

US3432202
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:27:13
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:52:41

FDA-CBER-2022-1614-5928448

US3432202
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:52:41

FDA-CBER-2022-1614-5928449

US3432202
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:27:13
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:52:41

FDA-CBER-2022-1614-5928450

US3432202
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:27:13
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:52:41

FDA-CBER-2022-1614-5928451

US3432202
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:27:13
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:52:41

FDA-CBER-2022-1614-5928452

US3432202
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:27:13
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	16 Sep 2020 21:52:41

FDA-CBER-2022-1614-5928453

US3432202
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:27:13
Start Year (derived)

Audit	User	Time (GMT)
User entered '2017'	System	16 Sep 2020 21:52:41

FDA-CBER-2022-1614-5928454

US3432202
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:27:13
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:52:41

FDA-CBER-2022-1614-5928455

US3432202
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:27:13
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:52:41

FDA-CBER-2022-1614-5928456

US3432202
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 09:27:13
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Choreiform movements, PT: Chorea, LLT: Chorea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:54:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:54:43
Data point term sent to Coder	System	16 Sep 2020 21:53:26
User entered 'chorea'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:52:58

FDA-CBER-2022-1614-5928457

US3432202
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 09:27:13
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:52:58

FDA-CBER-2022-1614-5928458

US3432202
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:52:58

FDA-CBER-2022-1614-5928459

US3432202
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 09:27:13
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:52:58

FDA-CBER-2022-1614-5928460

US3432202
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 09:27:13
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:52:58

FDA-CBER-2022-1614-5928461

US3432202
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 09:27:13
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:52:58

FDA-CBER-2022-1614-5928462

US3432202
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 09:27:13
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	16 Sep 2020 21:52:58

FDA-CBER-2022-1614-5928463

US3432202
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 09:27:13
Start Year (derived)

Audit	User	Time (GMT)
User entered '2017'	System	16 Sep 2020 21:52:58

FDA-CBER-2022-1614-5928464

US3432202
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 09:27:13
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:52:58

FDA-CBER-2022-1614-5928465

US3432202
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 09:27:13
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:52:58

FDA-CBER-2022-1614-5928466

US3432202
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 09:27:13
Condition

Audit	User	Time (GMT)
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)	19 Oct 2020 18:51:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:51:24
Data point term sent to Coder	System	19 Oct 2020 18:50:27
User entered 'Hypertension'	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 18:49:27

FDA-CBER-2022-1614-5928467

US3432202
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 09:27:13
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN Jan 2020'	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 18:49:27

FDA-CBER-2022-1614-5928468

US3432202
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 18:49:27

FDA-CBER-2022-1614-5928469

US3432202
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 09:27:13
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 18:49:27

FDA-CBER-2022-1614-5928470

US3432202
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 09:27:13
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 18:49:27

FDA-CBER-2022-1614-5928471

US3432202
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 09:27:13
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 18:49:27

FDA-CBER-2022-1614-5928472

US3432202
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 09:27:13
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	19 Oct 2020 18:49:27

FDA-CBER-2022-1614-5928473

US3432202
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 09:27:13
Start Year (derived)

Audit	User	Time (GMT)
User entered '2020'	System	19 Oct 2020 18:49:27

FDA-CBER-2022-1614-5928474

US3432202
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 09:27:13
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:49:27

FDA-CBER-2022-1614-5928475

US3432202
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 09:27:13
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:49:27

FDA-CBER-2022-1614-5928476

US3432202
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 09:27:13
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:24:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:24:07
Data point term sent to Coder	System	20 Nov 2020 21:23:42
User entered 'Depression'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:23:04

FDA-CBER-2022-1614-5928477

US3432202
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 09:27:13
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:23:04

FDA-CBER-2022-1614-5928478

US3432202
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
User entered '1'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:23:04

FDA-CBER-2022-1614-5928479

US3432202
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 09:27:13
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:23:04

FDA-CBER-2022-1614-5928480

US3432202
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 09:27:13
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:23:04

FDA-CBER-2022-1614-5928481

US3432202
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 09:27:13
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:23:04

FDA-CBER-2022-1614-5928482

US3432202
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 09:27:13
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:23:04

FDA-CBER-2022-1614-5928483

US3432202
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 09:27:13
Start Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:23:04

FDA-CBER-2022-1614-5928484

US3432202
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 09:27:13
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:23:04

FDA-CBER-2022-1614-5928485

US3432202
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 09:27:13
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:23:04

FDA-CBER-2022-1614-5928486

US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:49:32

FDA-CBER-2022-1614-5928487

US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:49:32

FDA-CBER-2022-1614-5928488

US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '14:43'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:49:32

FDA-CBER-2022-1614-5928489

US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '19 Aug 2020 14:43'	System	19 Aug 2020 20:49:32

FDA-CBER-2022-1614-5928490

US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Height *(xxx.x)*

Audit	User	Time (GMT)
User entered '174' cm	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:49:32
DataPoint set to visible.	System	19 Aug 2020 18:42:29

FDA-CBER-2022-1614-5928491

US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Weight *(xxx.x)*

Audit	User	Time (GMT)
User entered '81.7' kg	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:49:32
DataPoint set to visible.	System	19 Aug 2020 18:42:29

FDA-CBER-2022-1614-5928492

US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
BMI *(xxx.x)*

Audit	User	Time (GMT)
Amendment Manager: User entered '26.98507'	System	17 Sep 2020 00:14:33
User entered '27.0'	System	19 Aug 2020 20:49:32
DataPoint set to visible.	System	19 Aug 2020 18:42:29

FDA-CBER-2022-1614-5928493

US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
BMI units

Audit	User	Time (GMT)
User entered 'kg/m2'	System	19 Aug 2020 20:49:32
DataPoint set to visible.	System	19 Aug 2020 18:42:29

FDA-CBER-2022-1614-5928494

US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 20:49:48
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Aug 2020 20:49:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:49:48
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 20:49:32
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:49:32

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US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Route of measurement

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 17:26:00
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:49:56
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 20:49:32
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:49:32

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US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
If Other, specify

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:49:32

FDA-CBER-2022-1614-5928497

US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Pulse *(xxx)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 20:49:48
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Aug 2020 20:49:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:49:48
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 20:49:32
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:49:32

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US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Aug 2020 20:49:48
User entered empty.	System	19 Aug 2020 20:49:32

FDA-CBER-2022-1614-5928499

US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 20:49:48
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Aug 2020 20:49:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:49:48
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 20:49:32
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:49:32

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US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Aug 2020 20:49:48
User entered empty.	System	19 Aug 2020 20:49:32

FDA-CBER-2022-1614-5928501

US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 20:49:48
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Aug 2020 20:49:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:49:48
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 20:49:32
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:49:32

FDA-CBER-2022-1614-5928502

US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 20:49:48
User entered empty.	System	19 Aug 2020 20:49:32

FDA-CBER-2022-1614-5928503

US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 20:49:48
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Aug 2020 20:49:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:49:48
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 20:49:32
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:49:32

FDA-CBER-2022-1614-5928504

US3432202
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 20:49:48
User entered empty.	System	19 Aug 2020 20:49:32

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US3432202
Folder: Screening
Form: Physical Examination
Generated On: 26 Nov 2020 09:27:13
Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:43:39

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US3432202
Folder: Screening
Form: Physical Examination
Generated On: 26 Nov 2020 09:27:13
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	24 Sep 2020 11:22:45
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 21:44:20
User entered '19 Aug 2020'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:43:39

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US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

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US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

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US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

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US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

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US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

FDA-CBER-2022-1614-5928512

US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

FDA-CBER-2022-1614-5928514

US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

FDA-CBER-2022-1614-5928515

US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

FDA-CBER-2022-1614-5928516

US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

FDA-CBER-2022-1614-5928517

US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

FDA-CBER-2022-1614-5928518

US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Other

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

FDA-CBER-2022-1614-5928519

US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Specify

Audit	User	Time (GMT)
User entered 'retired'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

FDA-CBER-2022-1614-5928520

US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

FDA-CBER-2022-1614-5928521

US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

FDA-CBER-2022-1614-5928522

US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

FDA-CBER-2022-1614-5928523

US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '1'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

FDA-CBER-2022-1614-5928524

US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

FDA-CBER-2022-1614-5928525

US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

FDA-CBER-2022-1614-5928526

US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Other

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

FDA-CBER-2022-1614-5928527

US3432202
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:27:13
Specify

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:50:35

FDA-CBER-2022-1614-5928528

US3432202
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13
Was this visit performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 18:42:40

FDA-CBER-2022-1614-5928529

US3432202
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 18:42:40

FDA-CBER-2022-1614-5928530

US3432202
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 18:42:40

FDA-CBER-2022-1614-5928531

US3432202
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT1'	System	19 Aug 2020 18:42:40

FDA-CBER-2022-1614-5928532

US3432202
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:27:13
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:04:46

FDA-CBER-2022-1614-5928533

US3432202
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:27:13
What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:38:57
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:38:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 18:04:46
User entered '187067' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:04:46

FDA-CBER-2022-1614-5928534

US3432202
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:27:13
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:04:46

FDA-CBER-2022-1614-5928535

US3432202
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:27:13

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

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:51:07

FDA-CBER-2022-1614-5928536

US3432202
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:27:13

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

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:51:07

FDA-CBER-2022-1614-5928537

US3432202
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:27:13
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:51:07

FDA-CBER-2022-1614-5928538

US3432202
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:27:13
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:51:07

FDA-CBER-2022-1614-5928539

US3432202
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:27:13
Liver Disease

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:51:07

FDA-CBER-2022-1614-5928540

US3432202
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:27:13
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:04
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:34:44

FDA-CBER-2022-1614-5928541

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 09:27:13
Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928542

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 09:27:13
Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928543

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 09:27:13
Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928544

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 09:27:13
Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928545

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928546

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928547

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928548

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '14:43'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928549

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '19 Aug 2020 14:43'	System	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928550

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered '37.2' C	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928551

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Route of measurement

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928552

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
If Other, specify

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928553

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Pulse *(xxx)*

Audit	User	Time (GMT)
User entered '98'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928554

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928555

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User entered '20'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928556

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928557

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '136'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928558

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928559

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '70'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928560

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928561

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 09:27:13
Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928562

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 09:27:13
Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928563

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928564

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928565

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928566

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	20 Aug 2020 17:26:23
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	19 Aug 2020 20:52:58
User entered '16:09'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928567

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '19 Aug 2020 16:09'	System	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928568

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered '37.4' C	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928569

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Route of measurement

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928570

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
If Other, specify

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928571

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Pulse *(xxx)*

Audit	User	Time (GMT)
User entered '95'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928572

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928573

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User entered '15'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928574

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928575

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '125'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928576

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928577

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '74'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928578

US3432202
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 20:52:58

FDA-CBER-2022-1614-5928579

US3432202
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 26 Nov 2020 09:27:13
Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:57:54

FDA-CBER-2022-1614-5928580

US3432202
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 26 Nov 2020 09:27:13
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:57:54

FDA-CBER-2022-1614-5928581

US3432202
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
Was study treatment given?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928582

US3432202
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928583

US3432202
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928584

US3432202
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
What was the study treatment?

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928585

US3432202
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928586

US3432202
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '15:39'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928587

US3432202
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
Treatment Date and Time (derived)

Audit	User	Time (GMT)
User entered '19 Aug 2020 15:39'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928588

US3432202
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928589

US3432202
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928590

US3432202
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928591

US3432202
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:27:13
Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:58:10

FDA-CBER-2022-1614-5928592

US3432202
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:27:13
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:58:10

FDA-CBER-2022-1614-5928593

US3432202
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:27:13
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '14:55'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:58:10

FDA-CBER-2022-1614-5928594

US3432202
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:27:13
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '19 Aug 2020 14:55'	System	19 Aug 2020 20:58:10

FDA-CBER-2022-1614-5928595

US3432202
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 26 Nov 2020 09:27:13
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:58:25

FDA-CBER-2022-1614-5928596

US3432202
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:27:13
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:58:25

FDA-CBER-2022-1614-5928597

US3432202
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:27:13
Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:58:25

FDA-CBER-2022-1614-5928598

US3432202
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:27:13
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
User entered '15:02'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:58:25

FDA-CBER-2022-1614-5928599

US3432202
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:27:13
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '19 Aug 2020 15:02'	System	19 Aug 2020 20:58:25

FDA-CBER-2022-1614-5928600

US3432202
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:27:13
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:58:25

FDA-CBER-2022-1614-5928601

US3432202
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:27:13
Was the sample collected?

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:58:25

FDA-CBER-2022-1614-5928602

US3432202
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:27:13
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:58:25

FDA-CBER-2022-1614-5928603

US3432202
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:27:13
Collection date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 20:58:25

FDA-CBER-2022-1614-5928604

US3432202
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:58:29

FDA-CBER-2022-1614-5928605

US3432202
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:58:29

FDA-CBER-2022-1614-5928606

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928607

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:09:51', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'bc296eaa-262c-4add-9dda-664322731362'	System	19 Aug 2020 20:10:41
User entered 'Yes (Y)'	System	19 Aug 2020 20:10:41

FDA-CBER-2022-1614-5928608

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:10:13', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'bc296eaa-262c-4add-9dda-664322731362'	System	19 Aug 2020 20:10:41
User entered '99.4'	System	19 Aug 2020 20:10:41

FDA-CBER-2022-1614-5928609

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:10:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'bc296eaa-262c-4add-9dda-664322731362'	System	19 Aug 2020 20:10:41
User entered 'No (N)'	System	19 Aug 2020 20:10:41

FDA-CBER-2022-1614-5928610

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:10:37', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'bc296eaa-262c-4add-9dda-664322731362'	System	19 Aug 2020 20:10:41
User entered '19 Aug 2020 16:10'	System	19 Aug 2020 20:10:41

FDA-CBER-2022-1614-5928611

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '19 Aug 2020 15:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928612

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '19 Aug 2020 18:29'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928613

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928614

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:05:58', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2506b62c-3beb-4fad-bab4-f4573f6a431f'	System	20 Aug 2020 00:06:45
User entered 'Yes (Y)'	System	20 Aug 2020 00:06:45

FDA-CBER-2022-1614-5928615

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:06:08', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2506b62c-3beb-4fad-bab4-f4573f6a431f'	System	20 Aug 2020 00:06:45
User entered '98.7'	System	20 Aug 2020 00:06:45

FDA-CBER-2022-1614-5928616

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:06:15', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2506b62c-3beb-4fad-bab4-f4573f6a431f'	System	20 Aug 2020 00:06:45
User entered 'No (N)'	System	20 Aug 2020 00:06:45

FDA-CBER-2022-1614-5928617

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:06:42', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2506b62c-3beb-4fad-bab4-f4573f6a431f'	System	20 Aug 2020 00:06:45
User entered '19 Aug 2020 20:06'	System	20 Aug 2020 00:06:45

FDA-CBER-2022-1614-5928618

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '19 Aug 2020 19:24'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928619

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928620

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 2'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928621

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:27:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:02:15', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '12f2eff2-b6be-481d-8476-79353dda8449'	System	21 Aug 2020 02:02:52
User entered 'Yes (Y)'	System	21 Aug 2020 02:02:52

FDA-CBER-2022-1614-5928622

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:27:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:02:29', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '12f2eff2-b6be-481d-8476-79353dda8449'	System	21 Aug 2020 02:02:52
User entered '99.2'	System	21 Aug 2020 02:02:52

FDA-CBER-2022-1614-5928623

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:27:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:02:35', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '12f2eff2-b6be-481d-8476-79353dda8449'	System	21 Aug 2020 02:02:52
User entered 'No (N)'	System	21 Aug 2020 02:02:52

FDA-CBER-2022-1614-5928624

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:02:47', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '12f2eff2-b6be-481d-8476-79353dda8449'	System	21 Aug 2020 02:02:52
User entered '20 Aug 2020 22:02'	System	21 Aug 2020 02:02:52

FDA-CBER-2022-1614-5928625

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928626

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928627

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 3'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928628

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:27:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:07:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2660c800-c9e7-49df-ba48-1e460e8a29d0'	System	22 Aug 2020 01:08:32
User entered 'Yes (Y)'	System	22 Aug 2020 01:08:32

FDA-CBER-2022-1614-5928629

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:27:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:07:30', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2660c800-c9e7-49df-ba48-1e460e8a29d0'	System	22 Aug 2020 01:08:32
User entered '99.7'	System	22 Aug 2020 01:08:32

FDA-CBER-2022-1614-5928630

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:27:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:07:42', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2660c800-c9e7-49df-ba48-1e460e8a29d0'	System	22 Aug 2020 01:08:32
User entered 'Yes (Y)'	System	22 Aug 2020 01:08:32

FDA-CBER-2022-1614-5928631

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:27:13
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
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)	26 Aug 2020 19:51:10
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 'medication recorded in log after safety call' (Site from System).	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:59:31
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	22 Aug 2020 01:08:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:08:11', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2660c800-c9e7-49df-ba48-1e460e8a29d0'	System	22 Aug 2020 01:08:32
User entered '1'	System	22 Aug 2020 01:08:32

FDA-CBER-2022-1614-5928632

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:27:13
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:08:11', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2660c800-c9e7-49df-ba48-1e460e8a29d0'	System	22 Aug 2020 01:08:32
User entered '0'	System	22 Aug 2020 01:08:32

FDA-CBER-2022-1614-5928633

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:08:26', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2660c800-c9e7-49df-ba48-1e460e8a29d0'	System	22 Aug 2020 01:08:32
User entered '21 Aug 2020 21:08'	System	22 Aug 2020 01:08:32

FDA-CBER-2022-1614-5928634

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928635

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928636

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 4'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928637

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:27:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:07:42', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '857af27d-8e62-413e-8431-98401481d656'	System	23 Aug 2020 00:09:21
User entered 'Yes (Y)'	System	23 Aug 2020 00:09:21

FDA-CBER-2022-1614-5928638

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:27:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:07:51', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '857af27d-8e62-413e-8431-98401481d656'	System	23 Aug 2020 00:09:21
User entered '98.7'	System	23 Aug 2020 00:09:21

FDA-CBER-2022-1614-5928639

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:27:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:07:58', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '857af27d-8e62-413e-8431-98401481d656'	System	23 Aug 2020 00:09:21
User entered 'Yes (Y)'	System	23 Aug 2020 00:09:21

FDA-CBER-2022-1614-5928640

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:27:13
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
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)	26 Aug 2020 19:51:15
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 'medication recorded after safety call' (Site from System).	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 13:00:04
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	23 Aug 2020 00:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:08:05', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '857af27d-8e62-413e-8431-98401481d656'	System	23 Aug 2020 00:09:21
User entered '1'	System	23 Aug 2020 00:09:21

FDA-CBER-2022-1614-5928641

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:27:13
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:08:05', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '857af27d-8e62-413e-8431-98401481d656'	System	23 Aug 2020 00:09:21
User entered '0'	System	23 Aug 2020 00:09:21

FDA-CBER-2022-1614-5928642

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:08:13', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '857af27d-8e62-413e-8431-98401481d656'	System	23 Aug 2020 00:09:21
User entered '22 Aug 2020 20:08'	System	23 Aug 2020 00:09:21

FDA-CBER-2022-1614-5928643

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928644

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928645

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 5'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928646

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:27:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:03:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a1aa04b3-7736-40f6-b45d-5946adc9703d'	System	23 Aug 2020 23:03:57
User entered 'Yes (Y)'	System	23 Aug 2020 23:03:57

FDA-CBER-2022-1614-5928647

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:27:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:03:33', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a1aa04b3-7736-40f6-b45d-5946adc9703d'	System	23 Aug 2020 23:03:57
User entered '98.4'	System	23 Aug 2020 23:03:57

FDA-CBER-2022-1614-5928648

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:27:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:03:46', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a1aa04b3-7736-40f6-b45d-5946adc9703d'	System	23 Aug 2020 23:03:57
User entered 'No (N)'	System	23 Aug 2020 23:03:57

FDA-CBER-2022-1614-5928649

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:03:55', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a1aa04b3-7736-40f6-b45d-5946adc9703d'	System	23 Aug 2020 23:03:57
User entered '23 Aug 2020 19:03'	System	23 Aug 2020 23:03:57

FDA-CBER-2022-1614-5928650

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928651

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928652

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 6'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928653

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:27:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:03:15', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f184329c-e3f6-4c86-8735-fa31bc05878f'	System	25 Aug 2020 04:04:00
User entered 'Yes (Y)'	System	25 Aug 2020 04:04:00

FDA-CBER-2022-1614-5928654

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:27:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:03:38', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f184329c-e3f6-4c86-8735-fa31bc05878f'	System	25 Aug 2020 04:04:00
User entered '98.9'	System	25 Aug 2020 04:04:00

FDA-CBER-2022-1614-5928655

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:27:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:03:45', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f184329c-e3f6-4c86-8735-fa31bc05878f'	System	25 Aug 2020 04:04:00
User entered 'No (N)'	System	25 Aug 2020 04:04:00

FDA-CBER-2022-1614-5928656

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:03:54', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f184329c-e3f6-4c86-8735-fa31bc05878f'	System	25 Aug 2020 04:04:00
User entered '25 Aug 2020 00:03'	System	25 Aug 2020 04:04:00

FDA-CBER-2022-1614-5928657

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928658

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928659

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 7'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928660

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:27:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:27:50', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fe323b35-c6e5-4f2a-86e3-4226c467028f'	System	26 Aug 2020 02:28:15
User entered 'Yes (Y)'	System	26 Aug 2020 02:28:15

FDA-CBER-2022-1614-5928661

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:27:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:27:59', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fe323b35-c6e5-4f2a-86e3-4226c467028f'	System	26 Aug 2020 02:28:15
User entered '96.9'	System	26 Aug 2020 02:28:15

FDA-CBER-2022-1614-5928662

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:27:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:28:03', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fe323b35-c6e5-4f2a-86e3-4226c467028f'	System	26 Aug 2020 02:28:15
User entered 'No (N)'	System	26 Aug 2020 02:28:15

FDA-CBER-2022-1614-5928663

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:28:10', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fe323b35-c6e5-4f2a-86e3-4226c467028f'	System	26 Aug 2020 02:28:15
User entered '25 Aug 2020 22:28'	System	26 Aug 2020 02:28:15

FDA-CBER-2022-1614-5928664

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928665

US3432202
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928666

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928667

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:13:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8da26fe2-5bf8-435c-980d-96e56d0b168b'	System	19 Aug 2020 20:13:39
User entered 'None (1)'	System	19 Aug 2020 20:13:39

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:13:04', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8da26fe2-5bf8-435c-980d-96e56d0b168b'	System	19 Aug 2020 20:13:39
User entered 'No (N)'	System	19 Aug 2020 20:13:39

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:13:08', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8da26fe2-5bf8-435c-980d-96e56d0b168b'	System	19 Aug 2020 20:13:39
User entered 'No (N)'	System	19 Aug 2020 20:13:39

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:13:26', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8da26fe2-5bf8-435c-980d-96e56d0b168b'	System	19 Aug 2020 20:13:39
User entered 'None (1)'	System	19 Aug 2020 20:13:39

FDA-CBER-2022-1614-5928671

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:13:34', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8da26fe2-5bf8-435c-980d-96e56d0b168b'	System	19 Aug 2020 20:13:39
User entered '19 Aug 2020 16:13'	System	19 Aug 2020 20:13:39

FDA-CBER-2022-1614-5928672

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '19 Aug 2020 15:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928673

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '19 Aug 2020 18:29'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928674

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928675

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:07:01', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6e2cb261-7370-449d-978f-3c3edcfa5e8e'	System	20 Aug 2020 00:07:50
User entered 'None (1)'	System	20 Aug 2020 00:07:50

FDA-CBER-2022-1614-5928676

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:07:07', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6e2cb261-7370-449d-978f-3c3edcfa5e8e'	System	20 Aug 2020 00:07:50
User entered 'No (N)'	System	20 Aug 2020 00:07:50

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:07:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6e2cb261-7370-449d-978f-3c3edcfa5e8e'	System	20 Aug 2020 00:07:50
User entered 'No (N)'	System	20 Aug 2020 00:07:50

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:07:38', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6e2cb261-7370-449d-978f-3c3edcfa5e8e'	System	20 Aug 2020 00:07:50
User entered 'None (1)'	System	20 Aug 2020 00:07:50

FDA-CBER-2022-1614-5928679

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:07:46', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6e2cb261-7370-449d-978f-3c3edcfa5e8e'	System	20 Aug 2020 00:07:50
User entered '19 Aug 2020 20:07'	System	20 Aug 2020 00:07:50

FDA-CBER-2022-1614-5928680

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '19 Aug 2020 19:24'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928681

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928682

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 2'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928683

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:27:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:03:28', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a6727e02-aaca-42bb-9079-eb15a84aa2e7'	System	21 Aug 2020 02:04:01
User entered 'None (1)'	System	21 Aug 2020 02:04:01

FDA-CBER-2022-1614-5928684

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:27:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:03:33', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a6727e02-aaca-42bb-9079-eb15a84aa2e7'	System	21 Aug 2020 02:04:01
User entered 'No (N)'	System	21 Aug 2020 02:04:01

FDA-CBER-2022-1614-5928685

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:27:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:03:37', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a6727e02-aaca-42bb-9079-eb15a84aa2e7'	System	21 Aug 2020 02:04:01
User entered 'No (N)'	System	21 Aug 2020 02:04:01

FDA-CBER-2022-1614-5928686

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:27:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:03:49', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a6727e02-aaca-42bb-9079-eb15a84aa2e7'	System	21 Aug 2020 02:04:01
User entered 'None (1)'	System	21 Aug 2020 02:04:01

FDA-CBER-2022-1614-5928687

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:03:57', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a6727e02-aaca-42bb-9079-eb15a84aa2e7'	System	21 Aug 2020 02:04:01
User entered '20 Aug 2020 22:03'	System	21 Aug 2020 02:04:01

FDA-CBER-2022-1614-5928688

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928689

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928690

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 3'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928691

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:27:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:08:54', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '1791fa1f-04e8-440b-a6b4-37a2afa846f9'	System	22 Aug 2020 01:09:51
User entered 'None (1)'	System	22 Aug 2020 01:09:51

FDA-CBER-2022-1614-5928692

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:27:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:08:58', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '1791fa1f-04e8-440b-a6b4-37a2afa846f9'	System	22 Aug 2020 01:09:51
User entered 'No (N)'	System	22 Aug 2020 01:09:51

FDA-CBER-2022-1614-5928693

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:27:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:09:07', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '1791fa1f-04e8-440b-a6b4-37a2afa846f9'	System	22 Aug 2020 01:09:51
User entered 'No (N)'	System	22 Aug 2020 01:09:51

FDA-CBER-2022-1614-5928694

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:27:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:09:34', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '1791fa1f-04e8-440b-a6b4-37a2afa846f9'	System	22 Aug 2020 01:09:51
User entered 'None (1)'	System	22 Aug 2020 01:09:51

FDA-CBER-2022-1614-5928695

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:09:48', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '1791fa1f-04e8-440b-a6b4-37a2afa846f9'	System	22 Aug 2020 01:09:51
User entered '21 Aug 2020 21:09'	System	22 Aug 2020 01:09:51

FDA-CBER-2022-1614-5928696

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928697

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928698

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 4'	System	19 Aug 2020 20:04:44

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:27:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:08:28', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6836f12b-be75-4f70-bda5-e69bc5ab9fd8'	System	23 Aug 2020 00:09:47
User entered 'None (1)'	System	23 Aug 2020 00:09:47

FDA-CBER-2022-1614-5928700

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:27:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:08:32', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6836f12b-be75-4f70-bda5-e69bc5ab9fd8'	System	23 Aug 2020 00:09:47
User entered 'No (N)'	System	23 Aug 2020 00:09:47

FDA-CBER-2022-1614-5928701

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:27:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:08:36', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6836f12b-be75-4f70-bda5-e69bc5ab9fd8'	System	23 Aug 2020 00:09:47
User entered 'No (N)'	System	23 Aug 2020 00:09:47

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:27:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:08:44', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6836f12b-be75-4f70-bda5-e69bc5ab9fd8'	System	23 Aug 2020 00:09:47
User entered 'None (1)'	System	23 Aug 2020 00:09:47

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:08:50', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6836f12b-be75-4f70-bda5-e69bc5ab9fd8'	System	23 Aug 2020 00:09:47
User entered '22 Aug 2020 20:08'	System	23 Aug 2020 00:09:47

FDA-CBER-2022-1614-5928704

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928705

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928706

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 5'	System	19 Aug 2020 20:04:44

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:27:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:04:15', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '14773892-24a1-4e95-bbce-0861969ab082'	System	23 Aug 2020 23:04:41
User entered 'None (1)'	System	23 Aug 2020 23:04:41

FDA-CBER-2022-1614-5928708

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:27:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:04:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '14773892-24a1-4e95-bbce-0861969ab082'	System	23 Aug 2020 23:04:41
User entered 'No (N)'	System	23 Aug 2020 23:04:41

FDA-CBER-2022-1614-5928709

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:27:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:04:23', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '14773892-24a1-4e95-bbce-0861969ab082'	System	23 Aug 2020 23:04:41
User entered 'No (N)'	System	23 Aug 2020 23:04:41

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:27:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:04:27', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '14773892-24a1-4e95-bbce-0861969ab082'	System	23 Aug 2020 23:04:41
User entered 'None (1)'	System	23 Aug 2020 23:04:41

FDA-CBER-2022-1614-5928711

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:04:38', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '14773892-24a1-4e95-bbce-0861969ab082'	System	23 Aug 2020 23:04:41
User entered '23 Aug 2020 19:04'	System	23 Aug 2020 23:04:41

FDA-CBER-2022-1614-5928712

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928713

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928714

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 6'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928715

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:27:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:04:05', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8f0ea925-8b82-4159-8008-6b86a16b6ed3'	System	25 Aug 2020 04:04:32
User entered 'None (1)'	System	25 Aug 2020 04:04:32

FDA-CBER-2022-1614-5928716

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:27:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:04:09', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8f0ea925-8b82-4159-8008-6b86a16b6ed3'	System	25 Aug 2020 04:04:32
User entered 'No (N)'	System	25 Aug 2020 04:04:32

FDA-CBER-2022-1614-5928717

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:27:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:04:12', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8f0ea925-8b82-4159-8008-6b86a16b6ed3'	System	25 Aug 2020 04:04:32
User entered 'No (N)'	System	25 Aug 2020 04:04:32

FDA-CBER-2022-1614-5928718

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:27:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:04:23', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8f0ea925-8b82-4159-8008-6b86a16b6ed3'	System	25 Aug 2020 04:04:32
User entered 'None (1)'	System	25 Aug 2020 04:04:32

FDA-CBER-2022-1614-5928719

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:04:30', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8f0ea925-8b82-4159-8008-6b86a16b6ed3'	System	25 Aug 2020 04:04:32
User entered '25 Aug 2020 00:04'	System	25 Aug 2020 04:04:32

FDA-CBER-2022-1614-5928720

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928721

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928722

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 7'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928723

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:27:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:28:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd49671aa-482c-49cf-a4c1-cc54b17c59a1'	System	26 Aug 2020 02:28:47
User entered 'None (1)'	System	26 Aug 2020 02:28:47

FDA-CBER-2022-1614-5928724

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:27:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:28:27', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd49671aa-482c-49cf-a4c1-cc54b17c59a1'	System	26 Aug 2020 02:28:47
User entered 'No (N)'	System	26 Aug 2020 02:28:47

FDA-CBER-2022-1614-5928725

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:27:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:28:35', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd49671aa-482c-49cf-a4c1-cc54b17c59a1'	System	26 Aug 2020 02:28:47
User entered 'No (N)'	System	26 Aug 2020 02:28:47

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:13

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:28:39', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd49671aa-482c-49cf-a4c1-cc54b17c59a1'	System	26 Aug 2020 02:28:47
User entered 'None (1)'	System	26 Aug 2020 02:28:47

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:28:44', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd49671aa-482c-49cf-a4c1-cc54b17c59a1'	System	26 Aug 2020 02:28:47
User entered '25 Aug 2020 22:28'	System	26 Aug 2020 02:28:47

FDA-CBER-2022-1614-5928728

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928729

US3432202
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928730

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928731

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:13:52', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd039f43d-c7df-4fdd-87e4-51c2dda5d7f1'	System	19 Aug 2020 20:15:08
User entered 'None (0)'	System	19 Aug 2020 20:15:08

FDA-CBER-2022-1614-5928732

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:13:57', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd039f43d-c7df-4fdd-87e4-51c2dda5d7f1'	System	19 Aug 2020 20:15:08
User entered 'None (0)'	System	19 Aug 2020 20:15:08

FDA-CBER-2022-1614-5928733

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:14:01', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd039f43d-c7df-4fdd-87e4-51c2dda5d7f1'	System	19 Aug 2020 20:15:08
User entered 'None (0)'	System	19 Aug 2020 20:15:08

FDA-CBER-2022-1614-5928734

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:14:12', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd039f43d-c7df-4fdd-87e4-51c2dda5d7f1'	System	19 Aug 2020 20:15:08
User entered 'None (0)'	System	19 Aug 2020 20:15:08

FDA-CBER-2022-1614-5928735

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:14:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd039f43d-c7df-4fdd-87e4-51c2dda5d7f1'	System	19 Aug 2020 20:15:08
User entered 'None (0)'	System	19 Aug 2020 20:15:08

FDA-CBER-2022-1614-5928736

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:14:28', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd039f43d-c7df-4fdd-87e4-51c2dda5d7f1'	System	19 Aug 2020 20:15:08
User entered 'None (0)'	System	19 Aug 2020 20:15:08

FDA-CBER-2022-1614-5928737

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:14:32', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd039f43d-c7df-4fdd-87e4-51c2dda5d7f1'	System	19 Aug 2020 20:15:08
User entered 'No (N)'	System	19 Aug 2020 20:15:08

FDA-CBER-2022-1614-5928738

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:14:48', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd039f43d-c7df-4fdd-87e4-51c2dda5d7f1'	System	19 Aug 2020 20:15:08
User entered '19 Aug 2020 16:14'	System	19 Aug 2020 20:15:08

FDA-CBER-2022-1614-5928739

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '19 Aug 2020 15:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928740

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '19 Aug 2020 18:29'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928741

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928742

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:08:08', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '21dda515-7393-4b2c-bdb0-25608f0efa0c'	System	20 Aug 2020 00:09:12
User entered 'None (0)'	System	20 Aug 2020 00:09:12

FDA-CBER-2022-1614-5928743

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:08:19', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '21dda515-7393-4b2c-bdb0-25608f0efa0c'	System	20 Aug 2020 00:09:12
User entered 'None (0)'	System	20 Aug 2020 00:09:12

FDA-CBER-2022-1614-5928744

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:08:25', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '21dda515-7393-4b2c-bdb0-25608f0efa0c'	System	20 Aug 2020 00:09:12
User entered 'None (0)'	System	20 Aug 2020 00:09:12

FDA-CBER-2022-1614-5928745

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:08:33', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '21dda515-7393-4b2c-bdb0-25608f0efa0c'	System	20 Aug 2020 00:09:12
User entered 'None (0)'	System	20 Aug 2020 00:09:12

FDA-CBER-2022-1614-5928746

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:08:39', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '21dda515-7393-4b2c-bdb0-25608f0efa0c'	System	20 Aug 2020 00:09:12
User entered 'None (0)'	System	20 Aug 2020 00:09:12

FDA-CBER-2022-1614-5928747

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:08:45', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '21dda515-7393-4b2c-bdb0-25608f0efa0c'	System	20 Aug 2020 00:09:12
User entered 'None (0)'	System	20 Aug 2020 00:09:12

FDA-CBER-2022-1614-5928748

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:08:52', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '21dda515-7393-4b2c-bdb0-25608f0efa0c'	System	20 Aug 2020 00:09:12
User entered 'No (N)'	System	20 Aug 2020 00:09:12

FDA-CBER-2022-1614-5928749

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:09:08', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '21dda515-7393-4b2c-bdb0-25608f0efa0c'	System	20 Aug 2020 00:09:12
User entered '19 Aug 2020 20:09'	System	20 Aug 2020 00:09:12

FDA-CBER-2022-1614-5928750

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '19 Aug 2020 19:24'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928751

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928752

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 2'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928753

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:04:16', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cb4c0c86-539b-417f-bd05-662a4086379c'	System	21 Aug 2020 02:05:24
User entered 'No interference with activity (1)'	System	21 Aug 2020 02:05:24

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:04:28', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cb4c0c86-539b-417f-bd05-662a4086379c'	System	21 Aug 2020 02:05:24
User entered 'None (0)'	System	21 Aug 2020 02:05:24

FDA-CBER-2022-1614-5928755

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:04:32', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cb4c0c86-539b-417f-bd05-662a4086379c'	System	21 Aug 2020 02:05:24
User entered 'None (0)'	System	21 Aug 2020 02:05:24

FDA-CBER-2022-1614-5928756

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:04:37', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cb4c0c86-539b-417f-bd05-662a4086379c'	System	21 Aug 2020 02:05:24
User entered 'None (0)'	System	21 Aug 2020 02:05:24

FDA-CBER-2022-1614-5928757

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:04:41', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cb4c0c86-539b-417f-bd05-662a4086379c'	System	21 Aug 2020 02:05:24
User entered 'None (0)'	System	21 Aug 2020 02:05:24

FDA-CBER-2022-1614-5928758

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:04:47', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cb4c0c86-539b-417f-bd05-662a4086379c'	System	21 Aug 2020 02:05:24
User entered 'None (0)'	System	21 Aug 2020 02:05:24

FDA-CBER-2022-1614-5928759

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:04:59', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cb4c0c86-539b-417f-bd05-662a4086379c'	System	21 Aug 2020 02:05:24
User entered 'Yes (Y)'	System	21 Aug 2020 02:05:24

FDA-CBER-2022-1614-5928760

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:05:18', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cb4c0c86-539b-417f-bd05-662a4086379c'	System	21 Aug 2020 02:05:24
User entered '20 Aug 2020 22:05'	System	21 Aug 2020 02:05:24

FDA-CBER-2022-1614-5928761

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928762

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928763

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 3'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928764

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:10:11', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b81352cc-ccc6-4343-af77-5b4f9630140c'	System	22 Aug 2020 01:11:16
User entered 'No interference with activity (1)'	System	22 Aug 2020 01:11:16

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:10:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b81352cc-ccc6-4343-af77-5b4f9630140c'	System	22 Aug 2020 01:11:16
User entered 'No interference with activity (1)'	System	22 Aug 2020 01:11:16

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:10:26', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b81352cc-ccc6-4343-af77-5b4f9630140c'	System	22 Aug 2020 01:11:16
User entered 'None (0)'	System	22 Aug 2020 01:11:16

FDA-CBER-2022-1614-5928767

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:10:31', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b81352cc-ccc6-4343-af77-5b4f9630140c'	System	22 Aug 2020 01:11:16
User entered 'None (0)'	System	22 Aug 2020 01:11:16

FDA-CBER-2022-1614-5928768

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:10:36', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b81352cc-ccc6-4343-af77-5b4f9630140c'	System	22 Aug 2020 01:11:16
User entered 'None (0)'	System	22 Aug 2020 01:11:16

FDA-CBER-2022-1614-5928769

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:10:41', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b81352cc-ccc6-4343-af77-5b4f9630140c'	System	22 Aug 2020 01:11:16
User entered 'None (0)'	System	22 Aug 2020 01:11:16

FDA-CBER-2022-1614-5928770

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:10:54', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b81352cc-ccc6-4343-af77-5b4f9630140c'	System	22 Aug 2020 01:11:16
User entered 'Yes (Y)'	System	22 Aug 2020 01:11:16

FDA-CBER-2022-1614-5928771

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:11:12', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b81352cc-ccc6-4343-af77-5b4f9630140c'	System	22 Aug 2020 01:11:16
User entered '21 Aug 2020 21:11'	System	22 Aug 2020 01:11:16

FDA-CBER-2022-1614-5928772

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928773

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928774

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 4'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928775

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:09:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8bda09da-a3b7-47f6-a9cc-934951dba1a7'	System	23 Aug 2020 00:10:13
User entered 'No interference with activity (1)'	System	23 Aug 2020 00:10:13

FDA-CBER-2022-1614-5928776

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:09:28', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8bda09da-a3b7-47f6-a9cc-934951dba1a7'	System	23 Aug 2020 00:10:13
User entered 'No interference with activity (1)'	System	23 Aug 2020 00:10:13

FDA-CBER-2022-1614-5928777

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:09:32', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8bda09da-a3b7-47f6-a9cc-934951dba1a7'	System	23 Aug 2020 00:10:13
User entered 'None (0)'	System	23 Aug 2020 00:10:13

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:09:36', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8bda09da-a3b7-47f6-a9cc-934951dba1a7'	System	23 Aug 2020 00:10:13
User entered 'None (0)'	System	23 Aug 2020 00:10:13

FDA-CBER-2022-1614-5928779

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:09:40', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8bda09da-a3b7-47f6-a9cc-934951dba1a7'	System	23 Aug 2020 00:10:13
User entered 'None (0)'	System	23 Aug 2020 00:10:13

FDA-CBER-2022-1614-5928780

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:09:45', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8bda09da-a3b7-47f6-a9cc-934951dba1a7'	System	23 Aug 2020 00:10:13
User entered 'None (0)'	System	23 Aug 2020 00:10:13

FDA-CBER-2022-1614-5928781

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:09:52', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8bda09da-a3b7-47f6-a9cc-934951dba1a7'	System	23 Aug 2020 00:10:13
User entered 'No (N)'	System	23 Aug 2020 00:10:13

FDA-CBER-2022-1614-5928782

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:10:08', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8bda09da-a3b7-47f6-a9cc-934951dba1a7'	System	23 Aug 2020 00:10:13
User entered '22 Aug 2020 20:10'	System	23 Aug 2020 00:10:13

FDA-CBER-2022-1614-5928783

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928784

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928785

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 5'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928786

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:05:03', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fcb255f1-9380-4d06-a2cc-ac5dc71cad55'	System	23 Aug 2020 23:05:40
User entered 'No interference with activity (1)'	System	23 Aug 2020 23:05:40

FDA-CBER-2022-1614-5928787

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:05:10', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fcb255f1-9380-4d06-a2cc-ac5dc71cad55'	System	23 Aug 2020 23:05:40
User entered 'No interference with activity (1)'	System	23 Aug 2020 23:05:40

FDA-CBER-2022-1614-5928788

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:05:14', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fcb255f1-9380-4d06-a2cc-ac5dc71cad55'	System	23 Aug 2020 23:05:40
User entered 'None (0)'	System	23 Aug 2020 23:05:40

FDA-CBER-2022-1614-5928789

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:05:17', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fcb255f1-9380-4d06-a2cc-ac5dc71cad55'	System	23 Aug 2020 23:05:40
User entered 'None (0)'	System	23 Aug 2020 23:05:40

FDA-CBER-2022-1614-5928790

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:05:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fcb255f1-9380-4d06-a2cc-ac5dc71cad55'	System	23 Aug 2020 23:05:40
User entered 'None (0)'	System	23 Aug 2020 23:05:40

FDA-CBER-2022-1614-5928791

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:05:26', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fcb255f1-9380-4d06-a2cc-ac5dc71cad55'	System	23 Aug 2020 23:05:40
User entered 'None (0)'	System	23 Aug 2020 23:05:40

FDA-CBER-2022-1614-5928792

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:05:32', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fcb255f1-9380-4d06-a2cc-ac5dc71cad55'	System	23 Aug 2020 23:05:40
User entered 'No (N)'	System	23 Aug 2020 23:05:40

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:05:37', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fcb255f1-9380-4d06-a2cc-ac5dc71cad55'	System	23 Aug 2020 23:05:40
User entered '23 Aug 2020 19:05'	System	23 Aug 2020 23:05:40

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928795

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928796

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 6'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928797

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:27:13
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:04:41', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '23d916f2-6f67-45d7-9270-e41246d22428'	System	25 Aug 2020 04:05:38
User entered 'No interference with activity (1)'	System	25 Aug 2020 04:05:38

FDA-CBER-2022-1614-5928798

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:27:13
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:04:50', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '23d916f2-6f67-45d7-9270-e41246d22428'	System	25 Aug 2020 04:05:38
User entered 'No interference with activity (1)'	System	25 Aug 2020 04:05:38

FDA-CBER-2022-1614-5928799

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:27:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:04:55', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '23d916f2-6f67-45d7-9270-e41246d22428'	System	25 Aug 2020 04:05:38
User entered 'None (0)'	System	25 Aug 2020 04:05:38

FDA-CBER-2022-1614-5928800

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:27:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:05:01', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '23d916f2-6f67-45d7-9270-e41246d22428'	System	25 Aug 2020 04:05:38
User entered 'None (0)'	System	25 Aug 2020 04:05:38

FDA-CBER-2022-1614-5928801

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:27:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:05:06', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '23d916f2-6f67-45d7-9270-e41246d22428'	System	25 Aug 2020 04:05:38
User entered 'None (0)'	System	25 Aug 2020 04:05:38

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:27:13
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:05:11', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '23d916f2-6f67-45d7-9270-e41246d22428'	System	25 Aug 2020 04:05:38
User entered 'None (0)'	System	25 Aug 2020 04:05:38

FDA-CBER-2022-1614-5928803

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:05:16', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '23d916f2-6f67-45d7-9270-e41246d22428'	System	25 Aug 2020 04:05:38
User entered 'No (N)'	System	25 Aug 2020 04:05:38

FDA-CBER-2022-1614-5928804

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:05:33', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '23d916f2-6f67-45d7-9270-e41246d22428'	System	25 Aug 2020 04:05:38
User entered '25 Aug 2020 00:05'	System	25 Aug 2020 04:05:38

FDA-CBER-2022-1614-5928805

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928806

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928807

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 7'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928808

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:29:11', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5b2bbc6e-8a78-4fec-8a06-5ce82de9e855'	System	26 Aug 2020 02:29:53
User entered 'No interference with activity (1)'	System	26 Aug 2020 02:29:53

FDA-CBER-2022-1614-5928809

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:29:22', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5b2bbc6e-8a78-4fec-8a06-5ce82de9e855'	System	26 Aug 2020 02:29:53
User entered 'No interference with activity (1)'	System	26 Aug 2020 02:29:53

FDA-CBER-2022-1614-5928810

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:29:26', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5b2bbc6e-8a78-4fec-8a06-5ce82de9e855'	System	26 Aug 2020 02:29:53
User entered 'None (0)'	System	26 Aug 2020 02:29:53

FDA-CBER-2022-1614-5928811

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:29:30', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5b2bbc6e-8a78-4fec-8a06-5ce82de9e855'	System	26 Aug 2020 02:29:53
User entered 'None (0)'	System	26 Aug 2020 02:29:53

FDA-CBER-2022-1614-5928812

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:29:36', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5b2bbc6e-8a78-4fec-8a06-5ce82de9e855'	System	26 Aug 2020 02:29:53
User entered 'None (0)'	System	26 Aug 2020 02:29:53

FDA-CBER-2022-1614-5928813

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:29:41', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5b2bbc6e-8a78-4fec-8a06-5ce82de9e855'	System	26 Aug 2020 02:29:53
User entered 'None (0)'	System	26 Aug 2020 02:29:53

FDA-CBER-2022-1614-5928814

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:29:45', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5b2bbc6e-8a78-4fec-8a06-5ce82de9e855'	System	26 Aug 2020 02:29:53
User entered 'No (N)'	System	26 Aug 2020 02:29:53

FDA-CBER-2022-1614-5928815

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:29:49', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5b2bbc6e-8a78-4fec-8a06-5ce82de9e855'	System	26 Aug 2020 02:29:53
User entered '25 Aug 2020 22:29'	System	26 Aug 2020 02:29:53

FDA-CBER-2022-1614-5928816

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928817

US3432202
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5928818

US3432202
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 04:05:38
User entered 'Day 8'	System	25 Aug 2020 04:05:38

FDA-CBER-2022-1614-5928819

US3432202
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 26 Nov 2020 09:27:13
Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-26T22:14:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd467e7b9-2f7a-43dd-bc1e-d00f2420c8a7'	System	27 Aug 2020 02:14:33
User entered 'None (0)'	System	27 Aug 2020 02:14:33

FDA-CBER-2022-1614-5928820

US3432202
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-26T22:14:30', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd467e7b9-2f7a-43dd-bc1e-d00f2420c8a7'	System	27 Aug 2020 02:14:33
User entered '26 Aug 2020 22:14'	System	27 Aug 2020 02:14:33

FDA-CBER-2022-1614-5928821

US3432202
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 04:05:38

FDA-CBER-2022-1614-5928822

US3432202
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 04:05:38

FDA-CBER-2022-1614-5928823

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 04:05:38
User entered 'Day 8'	System	25 Aug 2020 04:05:38

FDA-CBER-2022-1614-5928824

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 26 Nov 2020 09:27:13
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-26T22:14:40', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '49d4db94-36f7-4078-94bc-21521f594dbf'	System	27 Aug 2020 02:14:48
User entered 'No interference with activity (1)'	System	27 Aug 2020 02:14:48

FDA-CBER-2022-1614-5928825

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-26T22:14:45', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '49d4db94-36f7-4078-94bc-21521f594dbf'	System	27 Aug 2020 02:14:48
User entered '26 Aug 2020 22:14'	System	27 Aug 2020 02:14:48

FDA-CBER-2022-1614-5928826

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 04:05:38

FDA-CBER-2022-1614-5928827

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 04:05:38

FDA-CBER-2022-1614-5928828

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 02:29:53
User entered 'Day 9'	System	26 Aug 2020 02:29:53

FDA-CBER-2022-1614-5928829

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 26 Nov 2020 09:27:13
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-27T12:01:01', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'aa5642a1-5e58-42fe-a319-dbdd4effb9af'	System	27 Aug 2020 16:01:14
User entered 'No interference with activity (1)'	System	27 Aug 2020 16:01:14

FDA-CBER-2022-1614-5928830

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-27T12:01:05', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'aa5642a1-5e58-42fe-a319-dbdd4effb9af'	System	27 Aug 2020 16:01:14
User entered '27 Aug 2020 12:01'	System	27 Aug 2020 16:01:14

FDA-CBER-2022-1614-5928831

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 02:29:53

FDA-CBER-2022-1614-5928832

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 02:29:53

FDA-CBER-2022-1614-5928833

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(10)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 02:14:48
User entered 'Day 10'	System	27 Aug 2020 02:14:48

FDA-CBER-2022-1614-5928834

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(10)
Generated On: 26 Nov 2020 09:27:13
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-28T21:12:03', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6f257b4d-2560-4d12-b469-88cd75b76a26'	System	29 Aug 2020 01:12:13
User entered 'Some interference with activity (2)'	System	29 Aug 2020 01:12:13

FDA-CBER-2022-1614-5928835

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(10)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-28T21:12:10', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6f257b4d-2560-4d12-b469-88cd75b76a26'	System	29 Aug 2020 01:12:13
User entered '28 Aug 2020 21:12'	System	29 Aug 2020 01:12:13

FDA-CBER-2022-1614-5928836

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(10)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 02:14:48

FDA-CBER-2022-1614-5928837

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(10)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 02:14:48

FDA-CBER-2022-1614-5928838

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(11)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 16:01:14
User entered 'Day 11'	System	27 Aug 2020 16:01:14

FDA-CBER-2022-1614-5928839

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(11)
Generated On: 26 Nov 2020 09:27:13
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-29T12:57:26', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '77563e9f-47e6-4afc-8cd8-0cece1bad412'	System	29 Aug 2020 16:57:34
User entered 'No interference with activity (1)'	System	29 Aug 2020 16:57:34

FDA-CBER-2022-1614-5928840

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(11)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-29T12:57:31', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '77563e9f-47e6-4afc-8cd8-0cece1bad412'	System	29 Aug 2020 16:57:34
User entered '29 Aug 2020 12:57'	System	29 Aug 2020 16:57:34

FDA-CBER-2022-1614-5928841

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(11)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 16:01:14

FDA-CBER-2022-1614-5928842

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(11)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 16:01:14

FDA-CBER-2022-1614-5928843

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(12)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 01:12:13
User entered 'Day 12'	System	29 Aug 2020 01:12:13

FDA-CBER-2022-1614-5928844

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(12)
Generated On: 26 Nov 2020 09:27:13
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-30T19:53:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '758887af-91df-487b-b3fd-388e22a55cdb'	System	30 Aug 2020 23:53:07
User entered 'No interference with activity (1)'	System	30 Aug 2020 23:53:07

FDA-CBER-2022-1614-5928845

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(12)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-30T19:53:04', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '758887af-91df-487b-b3fd-388e22a55cdb'	System	30 Aug 2020 23:53:07
User entered '30 Aug 2020 19:53'	System	30 Aug 2020 23:53:07

FDA-CBER-2022-1614-5928846

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(12)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 01:12:13

FDA-CBER-2022-1614-5928847

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(12)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 01:12:13

FDA-CBER-2022-1614-5928848

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(13)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 16:57:34
User entered 'Day 13'	System	29 Aug 2020 16:57:34

FDA-CBER-2022-1614-5928849

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(13)
Generated On: 26 Nov 2020 09:27:13
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-31T15:40:35', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '4f18423a-7b82-4706-af14-09672390c2d0'	System	31 Aug 2020 19:40:42
User entered 'No interference with activity (1)'	System	31 Aug 2020 19:40:42

FDA-CBER-2022-1614-5928850

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(13)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-31T15:40:40', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '4f18423a-7b82-4706-af14-09672390c2d0'	System	31 Aug 2020 19:40:42
User entered '31 Aug 2020 15:40'	System	31 Aug 2020 19:40:42

FDA-CBER-2022-1614-5928851

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(13)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 16:57:34

FDA-CBER-2022-1614-5928852

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(13)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 16:57:34

FDA-CBER-2022-1614-5928853

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(14)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Aug 2020 23:53:07
User entered 'Day 14'	System	30 Aug 2020 23:53:07

FDA-CBER-2022-1614-5928854

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(14)
Generated On: 26 Nov 2020 09:27:13
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-01T12:26:02', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '80ab8166-62af-4142-8646-2ab1075a79ce'	System	01 Sep 2020 16:26:07
User entered 'None (0)'	System	01 Sep 2020 16:26:07

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(14)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-01T12:26:04', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '80ab8166-62af-4142-8646-2ab1075a79ce'	System	01 Sep 2020 16:26:07
User entered '01 Sep 2020 12:26'	System	01 Sep 2020 16:26:07

FDA-CBER-2022-1614-5928856

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(14)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 23:53:07

FDA-CBER-2022-1614-5928857

US3432202
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(14)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 23:53:07

FDA-CBER-2022-1614-5928858

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 04:05:38
User entered 'Day 8'	System	25 Aug 2020 04:05:38

FDA-CBER-2022-1614-5928859

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-26T22:14:55', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd987f8ec-9815-438c-b47c-1e2faef9d21e'	System	27 Aug 2020 02:15:07
User entered 'No (N)'	System	27 Aug 2020 02:15:07

FDA-CBER-2022-1614-5928860

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-26T22:14:59', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd987f8ec-9815-438c-b47c-1e2faef9d21e'	System	27 Aug 2020 02:15:07
User entered '26 Aug 2020 22:14'	System	27 Aug 2020 02:15:07

FDA-CBER-2022-1614-5928861

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 04:05:38

FDA-CBER-2022-1614-5928862

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 04:05:38

FDA-CBER-2022-1614-5928863

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	27 Aug 2020 02:14:48
DataPoint Inactivated.	System	27 Aug 2020 02:14:33
Data entry locked.	System	26 Aug 2020 02:29:53
User entered 'Day 9'	System	26 Aug 2020 02:29:53

FDA-CBER-2022-1614-5928864

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-27T12:01:12', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '441e303f-1c8f-4911-bcd9-1a1b3067b702'	System	27 Aug 2020 16:01:27
User entered 'No (N)'	System	27 Aug 2020 16:01:27
DataPoint Activated.	System	27 Aug 2020 02:14:48
DataPoint Inactivated.	System	27 Aug 2020 02:14:33

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-27T12:01:15', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '441e303f-1c8f-4911-bcd9-1a1b3067b702'	System	27 Aug 2020 16:01:27
User entered '27 Aug 2020 12:01'	System	27 Aug 2020 16:01:27
DataPoint Activated.	System	27 Aug 2020 02:14:48
DataPoint Inactivated.	System	27 Aug 2020 02:14:33

FDA-CBER-2022-1614-5928866

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
DataPoint Activated.	System	27 Aug 2020 02:14:48
DataPoint Inactivated.	System	27 Aug 2020 02:14:33
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 02:29:53

FDA-CBER-2022-1614-5928867

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
DataPoint Activated.	System	27 Aug 2020 02:14:48
DataPoint Inactivated.	System	27 Aug 2020 02:14:33
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 02:29:53

FDA-CBER-2022-1614-5928868

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 02:14:48
User entered 'Day 10'	System	27 Aug 2020 02:14:48

FDA-CBER-2022-1614-5928869

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-28T21:12:17', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6984c51a-52fd-43e4-8524-20916b9cb7c0'	System	29 Aug 2020 01:12:23
User entered 'No (N)'	System	29 Aug 2020 01:12:23

FDA-CBER-2022-1614-5928870

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-28T21:12:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6984c51a-52fd-43e4-8524-20916b9cb7c0'	System	29 Aug 2020 01:12:23
User entered '28 Aug 2020 21:12'	System	29 Aug 2020 01:12:23

FDA-CBER-2022-1614-5928871

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 02:14:48

FDA-CBER-2022-1614-5928872

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 02:14:48

FDA-CBER-2022-1614-5928873

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 16:01:14
User entered 'Day 11'	System	27 Aug 2020 16:01:14

FDA-CBER-2022-1614-5928874

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-29T12:57:38', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e068e47d-256c-4ddc-814d-2ef432ef1942'	System	29 Aug 2020 16:57:45
User entered 'No (N)'	System	29 Aug 2020 16:57:45

FDA-CBER-2022-1614-5928875

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-29T12:57:42', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e068e47d-256c-4ddc-814d-2ef432ef1942'	System	29 Aug 2020 16:57:45
User entered '29 Aug 2020 12:57'	System	29 Aug 2020 16:57:45

FDA-CBER-2022-1614-5928876

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 16:01:14

FDA-CBER-2022-1614-5928877

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 16:01:14

FDA-CBER-2022-1614-5928878

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 01:12:13
User entered 'Day 12'	System	29 Aug 2020 01:12:13

FDA-CBER-2022-1614-5928879

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-30T19:53:13', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e19a6529-07dc-471b-b982-f08321ecfa89'	System	30 Aug 2020 23:53:23
User entered 'No (N)'	System	30 Aug 2020 23:53:23

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-30T19:53:18', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e19a6529-07dc-471b-b982-f08321ecfa89'	System	30 Aug 2020 23:53:23
User entered '30 Aug 2020 19:53'	System	30 Aug 2020 23:53:23

FDA-CBER-2022-1614-5928881

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 01:12:13

FDA-CBER-2022-1614-5928882

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 01:12:13

FDA-CBER-2022-1614-5928883

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 16:57:34
User entered 'Day 13'	System	29 Aug 2020 16:57:34

FDA-CBER-2022-1614-5928884

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-31T15:40:48', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '0abcd49e-8080-4316-889b-33cec902d715'	System	31 Aug 2020 19:40:54
User entered 'No (N)'	System	31 Aug 2020 19:40:54

FDA-CBER-2022-1614-5928885

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-31T15:40:51', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '0abcd49e-8080-4316-889b-33cec902d715'	System	31 Aug 2020 19:40:54
User entered '31 Aug 2020 15:40'	System	31 Aug 2020 19:40:54

FDA-CBER-2022-1614-5928886

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 16:57:34

FDA-CBER-2022-1614-5928887

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 16:57:34

FDA-CBER-2022-1614-5928888

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Aug 2020 23:53:07
User entered 'Day 14'	System	30 Aug 2020 23:53:07

FDA-CBER-2022-1614-5928889

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-01T12:26:12', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '62e2a789-5573-49a6-8434-cdbf9cff7d55'	System	01 Sep 2020 16:26:19
User entered 'No (N)'	System	01 Sep 2020 16:26:19

FDA-CBER-2022-1614-5928890

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-01T12:26:16', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '62e2a789-5573-49a6-8434-cdbf9cff7d55'	System	01 Sep 2020 16:26:19
User entered '01 Sep 2020 12:26'	System	01 Sep 2020 16:26:19

FDA-CBER-2022-1614-5928891

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 23:53:07

FDA-CBER-2022-1614-5928892

US3432202
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 23:53:07

FDA-CBER-2022-1614-5928893

US3432202
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:56:39

FDA-CBER-2022-1614-5928894

US3432202
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:56:39

FDA-CBER-2022-1614-5928895

US3432202
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:56:39

FDA-CBER-2022-1614-5928896

US3432202
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	26 Aug 2020 21:56:39

FDA-CBER-2022-1614-5928897

US3432202
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:11

FDA-CBER-2022-1614-5928898

US3432202
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 21:58:11

FDA-CBER-2022-1614-5928899

US3432202
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	02 Sep 2020 21:41:26

FDA-CBER-2022-1614-5928900

US3432202
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '02 Sep 2020' reason for change: Data Entry Error	Xhoi Mitre (b) (4) (b) (4)	10 Nov 2020 15:09:39
User entered '2 Sep 2020'	Phoebe Cunningham (b) (4)	02 Sep 2020 21:41:26

FDA-CBER-2022-1614-5928901

US3432202
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	02 Sep 2020 21:41:26

FDA-CBER-2022-1614-5928902

US3432202
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	02 Sep 2020 21:41:26

FDA-CBER-2022-1614-5928903

US3432202
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	02 Sep 2020 21:41:30

FDA-CBER-2022-1614-5928904

US3432202
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:41:30

FDA-CBER-2022-1614-5928905

US3432202
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Megan Powell (b) (4) (b) (4)	09 Sep 2020 23:48:51

FDA-CBER-2022-1614-5928906

US3432202
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '09 Sep 2020' reason for change: Per Query Resolution	Xhoi Mitre (b) (4) (b) (4)	10 Nov 2020 15:13:05
User entered '9 Sep 2020'	Megan Powell (b) (4) (b) (4)	09 Sep 2020 23:48:51

FDA-CBER-2022-1614-5928907

US3432202
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Megan Powell (b) (4) (b) (4)	09 Sep 2020 23:48:51

FDA-CBER-2022-1614-5928908

US3432202
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Sep 2020 23:48:51

FDA-CBER-2022-1614-5928909

US3432202
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 20:02:49

FDA-CBER-2022-1614-5928910

US3432202
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 20:02:49

FDA-CBER-2022-1614-5928911

US3432202
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13
Was this visit performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:44:20

FDA-CBER-2022-1614-5928912

US3432202
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:44:20

FDA-CBER-2022-1614-5928913

US3432202
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:44:20

FDA-CBER-2022-1614-5928914

US3432202
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT2'	System	16 Sep 2020 21:44:20

FDA-CBER-2022-1614-5928915

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928916

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928917

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928918

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '13:55'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928919

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '16 Sep 2020 13:55'	System	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928920

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered '37.1' C	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928921

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Route of measurement

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928922

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
If Other, specify

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928923

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Pulse *(xxx)*

Audit	User	Time (GMT)
User entered '95'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928924

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928925

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User entered '18'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928926

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928927

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '132'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928928

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928929

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '061'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928930

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:27:13
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928931

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928932

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928933

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928934

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '16:00'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928935

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '16 Sep 2020 16:00'	System	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928936

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered '97.1' F	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928937

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Route of measurement

Audit	User	Time (GMT)
User entered 'Other (Other)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928938

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
If Other, specify

Audit	User	Time (GMT)
User entered 'IR'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928939

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Pulse *(xxx)*

Audit	User	Time (GMT)
User entered '096'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928940

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928941

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User entered '16'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928942

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928943

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '138'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928944

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928945

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '067'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928946

US3432202
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:27:13
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 21:46:09

FDA-CBER-2022-1614-5928947

US3432202
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 09:27:13
Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:32

FDA-CBER-2022-1614-5928948

US3432202
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 09:27:13
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:32

FDA-CBER-2022-1614-5928949

US3432202
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
Was study treatment given?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928950

US3432202
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928951

US3432202
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928952

US3432202
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
What was the study treatment?

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928953

US3432202
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928954

US3432202
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '15:24'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928955

US3432202
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
Treatment Date and Time (derived)

Audit	User	Time (GMT)
User entered '16 Sep 2020 15:24'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928956

US3432202
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928957

US3432202
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928958

US3432202
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:27:13
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928959

US3432202
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:27:13
Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:50:05

FDA-CBER-2022-1614-5928960

US3432202
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:27:13
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:50:05

FDA-CBER-2022-1614-5928961

US3432202
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:27:13
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '14:20'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:50:05

FDA-CBER-2022-1614-5928962

US3432202
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:27:13
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '16 Sep 2020 14:20'	System	16 Sep 2020 21:50:05

FDA-CBER-2022-1614-5928963

US3432202
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 26 Nov 2020 09:27:13
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:50:21

FDA-CBER-2022-1614-5928964

US3432202
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:27:13
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:50:21

FDA-CBER-2022-1614-5928965

US3432202
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:27:13
Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:50:21

FDA-CBER-2022-1614-5928966

US3432202
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:27:13
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
User entered '14:22'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:50:21

FDA-CBER-2022-1614-5928967

US3432202
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:27:13
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '16 Sep 2020 14:22'	System	16 Sep 2020 21:50:21

FDA-CBER-2022-1614-5928968

US3432202
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:27:13
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:50:21

FDA-CBER-2022-1614-5928969

US3432202
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:27:13
Was the sample collected?

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:50:21

FDA-CBER-2022-1614-5928970

US3432202
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:27:13
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:50:21

FDA-CBER-2022-1614-5928971

US3432202
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:27:13
Collection date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:50:21

FDA-CBER-2022-1614-5928972

US3432202
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:50:27

FDA-CBER-2022-1614-5928973

US3432202
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 21:50:27

FDA-CBER-2022-1614-5928974

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928975

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:08:27', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ee7e7883-f298-41e3-95bf-7194ed0b08a5'	System	16 Sep 2020 20:09:12
User entered 'Yes (Y)'	System	16 Sep 2020 20:09:12

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:08:42', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ee7e7883-f298-41e3-95bf-7194ed0b08a5'	System	16 Sep 2020 20:09:12
User entered '97.1'	System	16 Sep 2020 20:09:12

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:08:50', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ee7e7883-f298-41e3-95bf-7194ed0b08a5'	System	16 Sep 2020 20:09:12
User entered 'Yes (Y)'	System	16 Sep 2020 20:09:12

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
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)	23 Nov 2020 07:33:27
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'yes' (Site from System).	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:38:40
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	16 Sep 2020 20:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:08:55', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ee7e7883-f298-41e3-95bf-7194ed0b08a5'	System	16 Sep 2020 20:09:12
User entered '1'	System	16 Sep 2020 20:09:12

FDA-CBER-2022-1614-5928979

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:08:55', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ee7e7883-f298-41e3-95bf-7194ed0b08a5'	System	16 Sep 2020 20:09:12
User entered '0'	System	16 Sep 2020 20:09:12

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:09:06', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ee7e7883-f298-41e3-95bf-7194ed0b08a5'	System	16 Sep 2020 20:09:12
User entered '16 Sep 2020 16:09'	System	16 Sep 2020 20:09:12

FDA-CBER-2022-1614-5928981

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '16 Sep 2020 15:44'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928982

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '16 Sep 2020 18:14'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928983

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928984

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:47:41', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f54988c7-baf6-488d-840f-4ef7dfff4308'	System	17 Sep 2020 01:48:16
User entered 'Yes (Y)'	System	17 Sep 2020 01:48:16

FDA-CBER-2022-1614-5928985

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:47:52', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f54988c7-baf6-488d-840f-4ef7dfff4308'	System	17 Sep 2020 01:48:16
User entered '99.1'	System	17 Sep 2020 01:48:16

FDA-CBER-2022-1614-5928986

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:48:03', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f54988c7-baf6-488d-840f-4ef7dfff4308'	System	17 Sep 2020 01:48:16
User entered 'Yes (Y)'	System	17 Sep 2020 01:48:16

FDA-CBER-2022-1614-5928987

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
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)	23 Nov 2020 07:33:32
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'yes' (Site from System).	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:39:38
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	17 Sep 2020 01:48:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:48:06', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f54988c7-baf6-488d-840f-4ef7dfff4308'	System	17 Sep 2020 01:48:16
User entered '1'	System	17 Sep 2020 01:48:16

FDA-CBER-2022-1614-5928988

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:48:06', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f54988c7-baf6-488d-840f-4ef7dfff4308'	System	17 Sep 2020 01:48:16
User entered '0'	System	17 Sep 2020 01:48:16

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:48:13', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f54988c7-baf6-488d-840f-4ef7dfff4308'	System	17 Sep 2020 01:48:16
User entered '16 Sep 2020 21:48'	System	17 Sep 2020 01:48:16

FDA-CBER-2022-1614-5928990

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '16 Sep 2020 19:09'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928991

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928992

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 2'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928993

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:27:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:02:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd84ea7ff-33c9-4339-9cf7-083ad7ce49a2'	System	17 Sep 2020 16:04:03
User entered 'Yes (Y)'	System	17 Sep 2020 16:04:03

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:27:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:02:23', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd84ea7ff-33c9-4339-9cf7-083ad7ce49a2'	System	17 Sep 2020 16:04:03
User entered '98.6'	System	17 Sep 2020 16:04:03

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:27:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:02:28', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd84ea7ff-33c9-4339-9cf7-083ad7ce49a2'	System	17 Sep 2020 16:04:03
User entered 'No (N)'	System	17 Sep 2020 16:04:03

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:02:40', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd84ea7ff-33c9-4339-9cf7-083ad7ce49a2'	System	17 Sep 2020 16:04:03
User entered '17 Sep 2020 12:02'	System	17 Sep 2020 16:04:03

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928998

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5928999

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 3'	System	16 Sep 2020 20:03:26

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:27:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:07:31', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '4d443e5c-4d1b-48d5-be7e-e91e902f2b72'	System	19 Sep 2020 04:08:04
User entered 'Yes (Y)'	System	19 Sep 2020 04:08:04

FDA-CBER-2022-1614-5929001

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:27:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:07:40', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '4d443e5c-4d1b-48d5-be7e-e91e902f2b72'	System	19 Sep 2020 04:08:04
User entered '96.6'	System	19 Sep 2020 04:08:04

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:27:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:07:48', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '4d443e5c-4d1b-48d5-be7e-e91e902f2b72'	System	19 Sep 2020 04:08:04
User entered 'No (N)'	System	19 Sep 2020 04:08:04

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:08:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '4d443e5c-4d1b-48d5-be7e-e91e902f2b72'	System	19 Sep 2020 04:08:04
User entered '19 Sep 2020 00:08'	System	19 Sep 2020 04:08:04

FDA-CBER-2022-1614-5929004

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929005

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929006

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 4'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929007

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:27:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:38:23', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '7d5a5232-c675-492b-9747-e0b73d808ccf'	System	20 Sep 2020 02:39:09
User entered 'Yes (Y)'	System	20 Sep 2020 02:39:09

FDA-CBER-2022-1614-5929008

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:27:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:38:46', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '7d5a5232-c675-492b-9747-e0b73d808ccf'	System	20 Sep 2020 02:39:09
User entered '98.0'	System	20 Sep 2020 02:39:09

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:27:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:38:52', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '7d5a5232-c675-492b-9747-e0b73d808ccf'	System	20 Sep 2020 02:39:09
User entered 'No (N)'	System	20 Sep 2020 02:39:09

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:39:04', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '7d5a5232-c675-492b-9747-e0b73d808ccf'	System	20 Sep 2020 02:39:09
User entered '19 Sep 2020 22:39'	System	20 Sep 2020 02:39:09

FDA-CBER-2022-1614-5929011

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929012

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929013

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 5'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929014

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:27:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:10:26', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '74b4e3ef-3216-4292-b796-c7ea9b28b4d9'	System	21 Sep 2020 02:11:31
User entered 'Yes (Y)'	System	21 Sep 2020 02:11:31

FDA-CBER-2022-1614-5929015

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:27:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:10:49', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '74b4e3ef-3216-4292-b796-c7ea9b28b4d9'	System	21 Sep 2020 02:11:31
User entered '97.4'	System	21 Sep 2020 02:11:31

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:27:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:11:02', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '74b4e3ef-3216-4292-b796-c7ea9b28b4d9'	System	21 Sep 2020 02:11:31
User entered 'No (N)'	System	21 Sep 2020 02:11:31

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:11:29', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '74b4e3ef-3216-4292-b796-c7ea9b28b4d9'	System	21 Sep 2020 02:11:31
User entered '20 Sep 2020 22:11'	System	21 Sep 2020 02:11:31

FDA-CBER-2022-1614-5929018

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929019

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929020

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 6'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929021

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929022

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929023

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 7'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929024

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:27:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T16:19:49', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e9bb1969-4b20-44fc-923a-3d17a8511017'	System	22 Sep 2020 20:20:52
User entered 'Yes (Y)'	System	22 Sep 2020 20:20:52

FDA-CBER-2022-1614-5929025

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:27:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T16:20:33', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e9bb1969-4b20-44fc-923a-3d17a8511017'	System	22 Sep 2020 20:20:52
User entered '97.5'	System	22 Sep 2020 20:20:52

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:27:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T16:20:38', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e9bb1969-4b20-44fc-923a-3d17a8511017'	System	22 Sep 2020 20:20:52
User entered 'No (N)'	System	22 Sep 2020 20:20:52

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T16:20:45', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e9bb1969-4b20-44fc-923a-3d17a8511017'	System	22 Sep 2020 20:20:52
User entered '22 Sep 2020 16:20'	System	22 Sep 2020 20:20:52

FDA-CBER-2022-1614-5929028

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929029

US3432202
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929030

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929031

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:09:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a1995a12-27a7-4e92-9c60-627408add54a'	System	16 Sep 2020 20:10:12
User entered 'None (1)'	System	16 Sep 2020 20:10:12

FDA-CBER-2022-1614-5929032

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:09:29', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a1995a12-27a7-4e92-9c60-627408add54a'	System	16 Sep 2020 20:10:12
User entered 'No (N)'	System	16 Sep 2020 20:10:12

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:10:01', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a1995a12-27a7-4e92-9c60-627408add54a'	System	16 Sep 2020 20:10:12
User entered 'No (N)'	System	16 Sep 2020 20:10:12

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:09:51', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a1995a12-27a7-4e92-9c60-627408add54a'	System	16 Sep 2020 20:10:12
User entered 'None (1)'	System	16 Sep 2020 20:10:12

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:10:08', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a1995a12-27a7-4e92-9c60-627408add54a'	System	16 Sep 2020 20:10:12
User entered '16 Sep 2020 16:10'	System	16 Sep 2020 20:10:12

FDA-CBER-2022-1614-5929036

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '16 Sep 2020 15:44'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929037

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '16 Sep 2020 18:14'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929038

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929039

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:48:29', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '7a5beaea-5ac8-4860-a06c-14e1328ec76f'	System	17 Sep 2020 01:48:53
User entered 'None (1)'	System	17 Sep 2020 01:48:53

FDA-CBER-2022-1614-5929040

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:48:33', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '7a5beaea-5ac8-4860-a06c-14e1328ec76f'	System	17 Sep 2020 01:48:53
User entered 'No (N)'	System	17 Sep 2020 01:48:53

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:48:36', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '7a5beaea-5ac8-4860-a06c-14e1328ec76f'	System	17 Sep 2020 01:48:53
User entered 'No (N)'	System	17 Sep 2020 01:48:53

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:48:41', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '7a5beaea-5ac8-4860-a06c-14e1328ec76f'	System	17 Sep 2020 01:48:53
User entered 'None (1)'	System	17 Sep 2020 01:48:53

FDA-CBER-2022-1614-5929043

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:48:50', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '7a5beaea-5ac8-4860-a06c-14e1328ec76f'	System	17 Sep 2020 01:48:53
User entered '16 Sep 2020 21:48'	System	17 Sep 2020 01:48:53

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '16 Sep 2020 19:09'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929045

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929046

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 2'	System	16 Sep 2020 20:03:26

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:27:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:02:53', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c290609e-c8d4-4c29-85be-9d702a6080e2'	System	17 Sep 2020 16:04:45
User entered 'None (1)'	System	17 Sep 2020 16:04:45

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:27:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:02:57', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c290609e-c8d4-4c29-85be-9d702a6080e2'	System	17 Sep 2020 16:04:45
User entered 'No (N)'	System	17 Sep 2020 16:04:45

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:27:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:01', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c290609e-c8d4-4c29-85be-9d702a6080e2'	System	17 Sep 2020 16:04:45
User entered 'No (N)'	System	17 Sep 2020 16:04:45

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:27:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:07', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c290609e-c8d4-4c29-85be-9d702a6080e2'	System	17 Sep 2020 16:04:45
User entered 'None (1)'	System	17 Sep 2020 16:04:45

FDA-CBER-2022-1614-5929051

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:14', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c290609e-c8d4-4c29-85be-9d702a6080e2'	System	17 Sep 2020 16:04:45
User entered '17 Sep 2020 12:03'	System	17 Sep 2020 16:04:45

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929053

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 3'	System	16 Sep 2020 20:03:26

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:27:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:08:17', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c7023014-6981-4633-b8ad-0a061233b38a'	System	19 Sep 2020 04:09:11
User entered 'None (1)'	System	19 Sep 2020 04:09:11

FDA-CBER-2022-1614-5929056

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:27:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:08:32', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c7023014-6981-4633-b8ad-0a061233b38a'	System	19 Sep 2020 04:09:11
User entered 'No (N)'	System	19 Sep 2020 04:09:11

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:27:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:08:43', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c7023014-6981-4633-b8ad-0a061233b38a'	System	19 Sep 2020 04:09:11
User entered 'No (N)'	System	19 Sep 2020 04:09:11

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:27:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:08:58', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c7023014-6981-4633-b8ad-0a061233b38a'	System	19 Sep 2020 04:09:11
User entered 'None (1)'	System	19 Sep 2020 04:09:11

FDA-CBER-2022-1614-5929059

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:09:07', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c7023014-6981-4633-b8ad-0a061233b38a'	System	19 Sep 2020 04:09:11
User entered '19 Sep 2020 00:09'	System	19 Sep 2020 04:09:11

FDA-CBER-2022-1614-5929060

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929061

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929062

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 4'	System	16 Sep 2020 20:03:26

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:27:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:40:06', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cba37acd-c61c-4044-80bc-c874d833633b'	System	20 Sep 2020 02:40:44
User entered 'None (1)'	System	20 Sep 2020 02:40:44

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:27:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:40:15', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cba37acd-c61c-4044-80bc-c874d833633b'	System	20 Sep 2020 02:40:44
User entered 'No (N)'	System	20 Sep 2020 02:40:44

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:27:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:40:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cba37acd-c61c-4044-80bc-c874d833633b'	System	20 Sep 2020 02:40:44
User entered 'No (N)'	System	20 Sep 2020 02:40:44

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:27:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:40:31', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cba37acd-c61c-4044-80bc-c874d833633b'	System	20 Sep 2020 02:40:44
User entered 'None (1)'	System	20 Sep 2020 02:40:44

FDA-CBER-2022-1614-5929067

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:40:40', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cba37acd-c61c-4044-80bc-c874d833633b'	System	20 Sep 2020 02:40:44
User entered '19 Sep 2020 22:40'	System	20 Sep 2020 02:40:44

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929069

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929070

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 5'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929071

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:27:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:11:36', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '621b24f6-0a67-485a-824c-815a2dd3ab97'	System	21 Sep 2020 02:12:19
User entered 'None (1)'	System	21 Sep 2020 02:12:19

FDA-CBER-2022-1614-5929072

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:27:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:11:42', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '621b24f6-0a67-485a-824c-815a2dd3ab97'	System	21 Sep 2020 02:12:19
User entered 'No (N)'	System	21 Sep 2020 02:12:19

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:27:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:11:58', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '621b24f6-0a67-485a-824c-815a2dd3ab97'	System	21 Sep 2020 02:12:19
User entered 'No (N)'	System	21 Sep 2020 02:12:19

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:27:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:12:06', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '621b24f6-0a67-485a-824c-815a2dd3ab97'	System	21 Sep 2020 02:12:19
User entered 'None (1)'	System	21 Sep 2020 02:12:19

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US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:12:15', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '621b24f6-0a67-485a-824c-815a2dd3ab97'	System	21 Sep 2020 02:12:19
User entered '20 Sep 2020 22:12'	System	21 Sep 2020 02:12:19

FDA-CBER-2022-1614-5929076

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929077

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929078

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 6'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929079

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929080

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929081

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 7'	System	16 Sep 2020 20:03:26

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:27:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:55:06', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9c125d19-2cc7-4e1f-8ec8-c4d12c9b099d'	System	22 Sep 2020 23:55:32
User entered 'None (1)'	System	22 Sep 2020 23:55:32

FDA-CBER-2022-1614-5929083

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:27:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:55:10', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9c125d19-2cc7-4e1f-8ec8-c4d12c9b099d'	System	22 Sep 2020 23:55:32
User entered 'No (N)'	System	22 Sep 2020 23:55:32

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:27:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:55:13', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9c125d19-2cc7-4e1f-8ec8-c4d12c9b099d'	System	22 Sep 2020 23:55:32
User entered 'No (N)'	System	22 Sep 2020 23:55:32

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:27:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:55:17', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9c125d19-2cc7-4e1f-8ec8-c4d12c9b099d'	System	22 Sep 2020 23:55:32
User entered 'None (1)'	System	22 Sep 2020 23:55:32

FDA-CBER-2022-1614-5929086

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:27:13
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:55:27', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9c125d19-2cc7-4e1f-8ec8-c4d12c9b099d'	System	22 Sep 2020 23:55:32
User entered '22 Sep 2020 19:55'	System	22 Sep 2020 23:55:32

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929088

US3432202
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929089

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929090

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:10:33', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6ed42d76-8105-4631-9069-89e37a54dc77'	System	16 Sep 2020 20:11:11
User entered 'None (0)'	System	16 Sep 2020 20:11:11

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:10:39', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6ed42d76-8105-4631-9069-89e37a54dc77'	System	16 Sep 2020 20:11:11
User entered 'None (0)'	System	16 Sep 2020 20:11:11

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:10:43', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6ed42d76-8105-4631-9069-89e37a54dc77'	System	16 Sep 2020 20:11:11
User entered 'None (0)'	System	16 Sep 2020 20:11:11

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:10:49', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6ed42d76-8105-4631-9069-89e37a54dc77'	System	16 Sep 2020 20:11:11
User entered 'None (0)'	System	16 Sep 2020 20:11:11

FDA-CBER-2022-1614-5929094

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:10:53', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6ed42d76-8105-4631-9069-89e37a54dc77'	System	16 Sep 2020 20:11:11
User entered 'None (0)'	System	16 Sep 2020 20:11:11

FDA-CBER-2022-1614-5929095

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:10:57', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6ed42d76-8105-4631-9069-89e37a54dc77'	System	16 Sep 2020 20:11:11
User entered 'None (0)'	System	16 Sep 2020 20:11:11

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:11:03', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6ed42d76-8105-4631-9069-89e37a54dc77'	System	16 Sep 2020 20:11:11
User entered 'No (N)'	System	16 Sep 2020 20:11:11

FDA-CBER-2022-1614-5929097

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:11:09', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6ed42d76-8105-4631-9069-89e37a54dc77'	System	16 Sep 2020 20:11:11
User entered '16 Sep 2020 16:11'	System	16 Sep 2020 20:11:11

FDA-CBER-2022-1614-5929098

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '16 Sep 2020 15:44'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929099

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '16 Sep 2020 18:14'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929100

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929101

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:49:01', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '47cc5d14-452f-4a18-9735-fccbcff6b1f0'	System	17 Sep 2020 01:49:37
User entered 'None (0)'	System	17 Sep 2020 01:49:37

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:49:07', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '47cc5d14-452f-4a18-9735-fccbcff6b1f0'	System	17 Sep 2020 01:49:37
User entered 'None (0)'	System	17 Sep 2020 01:49:37

FDA-CBER-2022-1614-5929103

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:49:11', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '47cc5d14-452f-4a18-9735-fccbcff6b1f0'	System	17 Sep 2020 01:49:37
User entered 'None (0)'	System	17 Sep 2020 01:49:37

FDA-CBER-2022-1614-5929104

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:49:15', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '47cc5d14-452f-4a18-9735-fccbcff6b1f0'	System	17 Sep 2020 01:49:37
User entered 'None (0)'	System	17 Sep 2020 01:49:37

FDA-CBER-2022-1614-5929105

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:49:18', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '47cc5d14-452f-4a18-9735-fccbcff6b1f0'	System	17 Sep 2020 01:49:37
User entered 'None (0)'	System	17 Sep 2020 01:49:37

FDA-CBER-2022-1614-5929106

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:49:22', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '47cc5d14-452f-4a18-9735-fccbcff6b1f0'	System	17 Sep 2020 01:49:37
User entered 'None (0)'	System	17 Sep 2020 01:49:37

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:49:26', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '47cc5d14-452f-4a18-9735-fccbcff6b1f0'	System	17 Sep 2020 01:49:37
User entered 'No (N)'	System	17 Sep 2020 01:49:37

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:49:30', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '47cc5d14-452f-4a18-9735-fccbcff6b1f0'	System	17 Sep 2020 01:49:37
User entered '16 Sep 2020 21:49'	System	17 Sep 2020 01:49:37

FDA-CBER-2022-1614-5929109

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '16 Sep 2020 19:09'	System	16 Sep 2020 20:03:26

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929111

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 2'	System	16 Sep 2020 20:03:26

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ed5faf4c-5c07-4eb4-ae28-3b70e3820961'	System	17 Sep 2020 16:05:03
User entered 'None (0)'	System	17 Sep 2020 16:05:03

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:24', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ed5faf4c-5c07-4eb4-ae28-3b70e3820961'	System	17 Sep 2020 16:05:03
User entered 'None (0)'	System	17 Sep 2020 16:05:03

FDA-CBER-2022-1614-5929114

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:28', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ed5faf4c-5c07-4eb4-ae28-3b70e3820961'	System	17 Sep 2020 16:05:03
User entered 'None (0)'	System	17 Sep 2020 16:05:03

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:32', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ed5faf4c-5c07-4eb4-ae28-3b70e3820961'	System	17 Sep 2020 16:05:03
User entered 'None (0)'	System	17 Sep 2020 16:05:03

FDA-CBER-2022-1614-5929116

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:35', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ed5faf4c-5c07-4eb4-ae28-3b70e3820961'	System	17 Sep 2020 16:05:03
User entered 'None (0)'	System	17 Sep 2020 16:05:03

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:40', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ed5faf4c-5c07-4eb4-ae28-3b70e3820961'	System	17 Sep 2020 16:05:03
User entered 'None (0)'	System	17 Sep 2020 16:05:03

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:47', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ed5faf4c-5c07-4eb4-ae28-3b70e3820961'	System	17 Sep 2020 16:05:03
User entered 'No (N)'	System	17 Sep 2020 16:05:03

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:50', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ed5faf4c-5c07-4eb4-ae28-3b70e3820961'	System	17 Sep 2020 16:05:03
User entered '17 Sep 2020 12:03'	System	17 Sep 2020 16:05:03

FDA-CBER-2022-1614-5929120

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929121

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929122

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 3'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929123

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:09:18', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '76fd99f7-5427-4a30-9214-442e19a6ad9f'	System	19 Sep 2020 04:10:24
User entered 'None (0)'	System	19 Sep 2020 04:10:24

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:09:26', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '76fd99f7-5427-4a30-9214-442e19a6ad9f'	System	19 Sep 2020 04:10:24
User entered 'None (0)'	System	19 Sep 2020 04:10:24

FDA-CBER-2022-1614-5929125

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:09:31', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '76fd99f7-5427-4a30-9214-442e19a6ad9f'	System	19 Sep 2020 04:10:24
User entered 'None (0)'	System	19 Sep 2020 04:10:24

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:09:35', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '76fd99f7-5427-4a30-9214-442e19a6ad9f'	System	19 Sep 2020 04:10:24
User entered 'None (0)'	System	19 Sep 2020 04:10:24

FDA-CBER-2022-1614-5929127

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:09:40', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '76fd99f7-5427-4a30-9214-442e19a6ad9f'	System	19 Sep 2020 04:10:24
User entered 'None (0)'	System	19 Sep 2020 04:10:24

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:09:46', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '76fd99f7-5427-4a30-9214-442e19a6ad9f'	System	19 Sep 2020 04:10:24
User entered 'None (0)'	System	19 Sep 2020 04:10:24

FDA-CBER-2022-1614-5929129

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:09:51', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '76fd99f7-5427-4a30-9214-442e19a6ad9f'	System	19 Sep 2020 04:10:24
User entered 'No (N)'	System	19 Sep 2020 04:10:24

FDA-CBER-2022-1614-5929130

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:10:06', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '76fd99f7-5427-4a30-9214-442e19a6ad9f'	System	19 Sep 2020 04:10:24
User entered '19 Sep 2020 00:10'	System	19 Sep 2020 04:10:24

FDA-CBER-2022-1614-5929131

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929132

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929133

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 4'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929134

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:40:54', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e5e831c1-44fd-4396-829c-f37ca6cda769'	System	20 Sep 2020 02:41:44
User entered 'None (0)'	System	20 Sep 2020 02:41:44

FDA-CBER-2022-1614-5929135

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:41:01', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e5e831c1-44fd-4396-829c-f37ca6cda769'	System	20 Sep 2020 02:41:44
User entered 'None (0)'	System	20 Sep 2020 02:41:44

FDA-CBER-2022-1614-5929136

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:41:07', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e5e831c1-44fd-4396-829c-f37ca6cda769'	System	20 Sep 2020 02:41:44
User entered 'None (0)'	System	20 Sep 2020 02:41:44

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:41:14', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e5e831c1-44fd-4396-829c-f37ca6cda769'	System	20 Sep 2020 02:41:44
User entered 'None (0)'	System	20 Sep 2020 02:41:44

FDA-CBER-2022-1614-5929138

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:41:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e5e831c1-44fd-4396-829c-f37ca6cda769'	System	20 Sep 2020 02:41:44
User entered 'None (0)'	System	20 Sep 2020 02:41:44

FDA-CBER-2022-1614-5929139

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:41:25', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e5e831c1-44fd-4396-829c-f37ca6cda769'	System	20 Sep 2020 02:41:44
User entered 'None (0)'	System	20 Sep 2020 02:41:44

FDA-CBER-2022-1614-5929140

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:41:30', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e5e831c1-44fd-4396-829c-f37ca6cda769'	System	20 Sep 2020 02:41:44
User entered 'No (N)'	System	20 Sep 2020 02:41:44

FDA-CBER-2022-1614-5929141

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:41:42', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e5e831c1-44fd-4396-829c-f37ca6cda769'	System	20 Sep 2020 02:41:44
User entered '19 Sep 2020 22:41'	System	20 Sep 2020 02:41:44

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929143

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929144

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 5'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929145

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:12:25', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8a587aed-e895-44af-b136-26ba8c9e6d65'	System	21 Sep 2020 02:13:22
User entered 'None (0)'	System	21 Sep 2020 02:13:22

FDA-CBER-2022-1614-5929146

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:12:41', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8a587aed-e895-44af-b136-26ba8c9e6d65'	System	21 Sep 2020 02:13:22
User entered 'None (0)'	System	21 Sep 2020 02:13:22

FDA-CBER-2022-1614-5929147

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:12:46', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8a587aed-e895-44af-b136-26ba8c9e6d65'	System	21 Sep 2020 02:13:22
User entered 'None (0)'	System	21 Sep 2020 02:13:22

FDA-CBER-2022-1614-5929148

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:12:52', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8a587aed-e895-44af-b136-26ba8c9e6d65'	System	21 Sep 2020 02:13:22
User entered 'None (0)'	System	21 Sep 2020 02:13:22

FDA-CBER-2022-1614-5929149

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:13:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8a587aed-e895-44af-b136-26ba8c9e6d65'	System	21 Sep 2020 02:13:22
User entered 'None (0)'	System	21 Sep 2020 02:13:22

FDA-CBER-2022-1614-5929150

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:13:08', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8a587aed-e895-44af-b136-26ba8c9e6d65'	System	21 Sep 2020 02:13:22
User entered 'None (0)'	System	21 Sep 2020 02:13:22

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:13:14', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8a587aed-e895-44af-b136-26ba8c9e6d65'	System	21 Sep 2020 02:13:22
User entered 'No (N)'	System	21 Sep 2020 02:13:22

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:13:17', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8a587aed-e895-44af-b136-26ba8c9e6d65'	System	21 Sep 2020 02:13:22
User entered '20 Sep 2020 22:13'	System	21 Sep 2020 02:13:22

FDA-CBER-2022-1614-5929153

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929154

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929155

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 6'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929156

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929157

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929158

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 7'	System	16 Sep 2020 20:03:26

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:55:41', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5fc0298e-44d5-4aeb-ab03-4218ef01441b'	System	22 Sep 2020 23:56:18
User entered 'None (0)'	System	22 Sep 2020 23:56:18

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:55:47', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5fc0298e-44d5-4aeb-ab03-4218ef01441b'	System	22 Sep 2020 23:56:18
User entered 'None (0)'	System	22 Sep 2020 23:56:18

FDA-CBER-2022-1614-5929161

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:55:52', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5fc0298e-44d5-4aeb-ab03-4218ef01441b'	System	22 Sep 2020 23:56:18
User entered 'None (0)'	System	22 Sep 2020 23:56:18

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:55:56', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5fc0298e-44d5-4aeb-ab03-4218ef01441b'	System	22 Sep 2020 23:56:18
User entered 'None (0)'	System	22 Sep 2020 23:56:18

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:56:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5fc0298e-44d5-4aeb-ab03-4218ef01441b'	System	22 Sep 2020 23:56:18
User entered 'None (0)'	System	22 Sep 2020 23:56:18

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:56:05', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5fc0298e-44d5-4aeb-ab03-4218ef01441b'	System	22 Sep 2020 23:56:18
User entered 'None (0)'	System	22 Sep 2020 23:56:18

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:56:08', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5fc0298e-44d5-4aeb-ab03-4218ef01441b'	System	22 Sep 2020 23:56:18
User entered 'No (N)'	System	22 Sep 2020 23:56:18

FDA-CBER-2022-1614-5929166

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:56:15', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5fc0298e-44d5-4aeb-ab03-4218ef01441b'	System	22 Sep 2020 23:56:18
User entered '22 Sep 2020 19:56'	System	22 Sep 2020 23:56:18

FDA-CBER-2022-1614-5929167

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
PC Open Date & Time

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929168

US3432202
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:27:13
PC Close Date & Time

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

FDA-CBER-2022-1614-5929169

US3432202
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Sep 2020 16:24:30

FDA-CBER-2022-1614-5929170

US3432202
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '26 Sep 2020'	Phoebe Cunningham (b) (4)	28 Sep 2020 16:24:30

FDA-CBER-2022-1614-5929171

US3432202
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	Phoebe Cunningham (b) (4)	28 Sep 2020 16:24:30

FDA-CBER-2022-1614-5929172

US3432202
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Called Pt. 9/25/2020 at 6:30pm, 9/26/2020 at 11:59am and 2:51pm. Also emailed participant on 9/26/2020.'	Phoebe Cunningham (b) (4)	28 Sep 2020 16:24:30

FDA-CBER-2022-1614-5929173

US3432202
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Sep 2020 16:24:39

FDA-CBER-2022-1614-5929174

US3432202
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 16:24:39

FDA-CBER-2022-1614-5929175

US3432202
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	02 Oct 2020 13:41:38

FDA-CBER-2022-1614-5929176

US3432202
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Phoebe Cunningham (b) (4)	02 Oct 2020 13:41:38

FDA-CBER-2022-1614-5929177

US3432202
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	Phoebe Cunningham (b) (4)	02 Oct 2020 13:41:38

FDA-CBER-2022-1614-5929178

US3432202
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'PT. CALLED ON 29SEP2020 AT 10:22AM, 30SEP2020 AT 6:34PM, AND 01OCT2020 AT 10:55AM AND 4:35PM. PT ALSO EMAILED ON 01OCT2020 AND NO CONTACT WAS MADE.' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	02 Oct 2020 13:41:53
User entered 'Pt. called on 29SEP2020 at 10:22am, 30SEP2020 at 6:34pm, and 01OCT2020 at 10:55am and 4:35pm. Pt also emailed on 01OCT2020 and not contact was made.'	Phoebe Cunningham (b) (4)	02 Oct 2020 13:41:38

FDA-CBER-2022-1614-5929179

US3432202
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	02 Oct 2020 13:42:01

FDA-CBER-2022-1614-5929180

US3432202
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 13:42:01

FDA-CBER-2022-1614-5929181

US3432202
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	13 Oct 2020 13:33:36

FDA-CBER-2022-1614-5929182

US3432202
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Phoebe Cunningham (b) (4)	13 Oct 2020 13:33:36

FDA-CBER-2022-1614-5929183

US3432202
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	Phoebe Cunningham (b) (4)	13 Oct 2020 13:33:36

FDA-CBER-2022-1614-5929184

US3432202
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'participant called 9:06 and 13:48 on 06OCT2020, 10:30 and 17:39 on 07OCT2020, and 9:44 08OCT2020'	Phoebe Cunningham (b) (4)	13 Oct 2020 13:33:36

FDA-CBER-2022-1614-5929185

US3432202
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:00:46

FDA-CBER-2022-1614-5929186

US3432202
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 21:00:46

FDA-CBER-2022-1614-5929187

US3432202
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13
Was this visit performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:00:57

FDA-CBER-2022-1614-5929188

US3432202
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 16:50:31
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Visit 3 was epiped for being out of window' (Site from System).	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:01:45
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	02 Nov 2020 21:00:57
User entered '2 Nov 2020'	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:00:57

US3432202
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:00:57

FDA-CBER-2022-1614-5929190

US3432202
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:27:13
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT3'	System	02 Nov 2020 21:00:57

FDA-CBER-2022-1614-5929191

US3432202
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:02:42

FDA-CBER-2022-1614-5929192

US3432202
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '2 Nov 2020'	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:02:42

FDA-CBER-2022-1614-5929193

US3432202
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '13:40'	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:02:42

FDA-CBER-2022-1614-5929194

US3432202
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '2 Nov 2020 13:40'	System	02 Nov 2020 21:02:42

FDA-CBER-2022-1614-5929195

US3432202
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered '36.7' C	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:02:42

FDA-CBER-2022-1614-5929196

US3432202
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Route of measurement

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:02:42

FDA-CBER-2022-1614-5929197

US3432202
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
If Other, specify

Audit	User	Time (GMT)
User entered empty.	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:02:42

FDA-CBER-2022-1614-5929198

US3432202
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Pulse *(xxx)*

Audit	User	Time (GMT)
User entered '097'	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:02:42

FDA-CBER-2022-1614-5929199

US3432202
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Nov 2020 21:02:42

FDA-CBER-2022-1614-5929200

US3432202
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User entered '015'	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:02:42

FDA-CBER-2022-1614-5929201

US3432202
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Nov 2020 21:02:42

FDA-CBER-2022-1614-5929202

US3432202
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '143'	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:02:42

FDA-CBER-2022-1614-5929203

US3432202
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Nov 2020 21:02:42

FDA-CBER-2022-1614-5929204

US3432202
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '068'	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:02:42

FDA-CBER-2022-1614-5929205

US3432202
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:27:13
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Nov 2020 21:02:42

FDA-CBER-2022-1614-5929206

US3432202
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 09:27:13
Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:02:49

FDA-CBER-2022-1614-5929207

US3432202
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 09:27:13
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:02:49

FDA-CBER-2022-1614-5929208

US3432202
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:27:13
Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:03:03

FDA-CBER-2022-1614-5929209

US3432202
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:27:13
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '2 Nov 2020'	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:03:03

FDA-CBER-2022-1614-5929210

US3432202
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:27:13
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '13:50'	Megan Powell (b) (4) (b) (4)	02 Nov 2020 21:03:03

FDA-CBER-2022-1614-5929211

US3432202
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:27:13
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '2 Nov 2020 13:50'	System	02 Nov 2020 21:03:03

FDA-CBER-2022-1614-5929212

US3432202
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 14:46:14

FDA-CBER-2022-1614-5929213

US3432202
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 14:46:14

FDA-CBER-2022-1614-5929214

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 64'	System	19 Aug 2020 20:04:44

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

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 (0e44f629885d0df0)', Time: '2020-10-21T09:10:45', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9dea5699-ae19-4496-afca-934ae34d967e'	System	21 Oct 2020 13:11:45
User entered 'Yes (Y)'	System	21 Oct 2020 13:11:45

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2020-10-21T09:10:51', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9dea5699-ae19-4496-afca-934ae34d967e'	System	21 Oct 2020 13:11:45
User entered 'No (N)'	System	21 Oct 2020 13:11:45

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-10-21T09:11:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9dea5699-ae19-4496-afca-934ae34d967e'	System	21 Oct 2020 13:11:45
User entered 'No (N)'	System	21 Oct 2020 13:11:45

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-10-21T09:11:07', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9dea5699-ae19-4496-afca-934ae34d967e'	System	21 Oct 2020 13:11:45
User entered 'Yes (Y)'	System	21 Oct 2020 13:11:45

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-10-21T09:11:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9dea5699-ae19-4496-afca-934ae34d967e'	System	21 Oct 2020 13:11:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Oct 2020 13:11:45

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-10-21T09:11:34', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9dea5699-ae19-4496-afca-934ae34d967e'	System	21 Oct 2020 13:11:45
User entered '21 Oct 2020 09:11:34'	System	21 Oct 2020 13:11:45

FDA-CBER-2022-1614-5929221

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5929222

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5929223

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 71'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5929224

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

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 (0e44f629885d0df0)', Time: '2020-10-28T12:16:45', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '3635c62d-f299-453c-bb4e-46bce14d54d3'	System	28 Oct 2020 16:17:09
User entered 'No (N)'	System	28 Oct 2020 16:17:09

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2020-10-28T12:16:51', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '3635c62d-f299-453c-bb4e-46bce14d54d3'	System	28 Oct 2020 16:17:09
User entered 'No (N)'	System	28 Oct 2020 16:17:09

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-10-28T12:16:59', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '3635c62d-f299-453c-bb4e-46bce14d54d3'	System	28 Oct 2020 16:17:09
User entered '28 Oct 2020 12:16:59'	System	28 Oct 2020 16:17:09

FDA-CBER-2022-1614-5929227

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 20:04:44

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 20:04:44

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 78'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5929230

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

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 (0e44f629885d0df0)', Time: '2020-11-04T11:54:51', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e346c949-9db5-40fc-990f-2f0de84dc10f'	System	04 Nov 2020 16:56:15
User entered 'Yes (Y)'	System	04 Nov 2020 16:56:15

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2020-11-04T11:54:56', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e346c949-9db5-40fc-990f-2f0de84dc10f'	System	04 Nov 2020 16:56:15
User entered 'No (N)'	System	04 Nov 2020 16:56:15

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-04T11:55:02', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e346c949-9db5-40fc-990f-2f0de84dc10f'	System	04 Nov 2020 16:56:15
User entered 'No (N)'	System	04 Nov 2020 16:56:15

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-04T11:55:13', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e346c949-9db5-40fc-990f-2f0de84dc10f'	System	04 Nov 2020 16:56:15
User entered 'Yes (Y)'	System	04 Nov 2020 16:56:15

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-04T11:55:31', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e346c949-9db5-40fc-990f-2f0de84dc10f'	System	04 Nov 2020 16:56:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Nov 2020 16:56:15

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-04T11:56:04', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e346c949-9db5-40fc-990f-2f0de84dc10f'	System	04 Nov 2020 16:56:15
User entered '04 Nov 2020 11:56:04'	System	04 Nov 2020 16:56:15

FDA-CBER-2022-1614-5929236

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5929237

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5929238

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 92'	System	19 Aug 2020 20:04:44

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

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 (0e44f629885d0df0)', Time: '2020-11-16T15:16:28', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2384f656-5d29-4ca9-88ac-1e7cd7f77b53'	System	16 Nov 2020 20:17:43
User entered 'Yes (Y)'	System	16 Nov 2020 20:17:43

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2020-11-16T15:16:39', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2384f656-5d29-4ca9-88ac-1e7cd7f77b53'	System	16 Nov 2020 20:17:43
User entered 'No (N)'	System	16 Nov 2020 20:17:43

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-16T15:16:46', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2384f656-5d29-4ca9-88ac-1e7cd7f77b53'	System	16 Nov 2020 20:17:43
User entered 'No (N)'	System	16 Nov 2020 20:17:43

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-16T15:16:56', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2384f656-5d29-4ca9-88ac-1e7cd7f77b53'	System	16 Nov 2020 20:17:43
User entered 'Yes (Y)'	System	16 Nov 2020 20:17:43

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-16T15:17:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2384f656-5d29-4ca9-88ac-1e7cd7f77b53'	System	16 Nov 2020 20:17:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Nov 2020 20:17:43

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-16T15:17:29', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2384f656-5d29-4ca9-88ac-1e7cd7f77b53'	System	16 Nov 2020 20:17:43
User entered '16 Nov 2020 15:17:29'	System	16 Nov 2020 20:17:43

FDA-CBER-2022-1614-5929245

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 20:04:44

US3432202
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 20:04:44
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 20:04:44

FDA-CBER-2022-1614-5929247

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929248

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '16 Oct 2020 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929249

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '20 Oct 2020 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929250

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929251

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '23 Oct 2020 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929252

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '27 Oct 2020 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929253

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929254

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '30 Oct 2020 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929255

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '03 Nov 2020 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929256

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 23:09:57

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '06 Nov 2020 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929258

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '10 Nov 2020 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929259

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929260

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '13 Nov 2020 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929261

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '17 Nov 2020 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929262

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929263

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

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 (0e44f629885d0df0)', Time: '2020-11-22T12:24:07', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '86700494-dfcf-4921-8515-07dbdd0ee4a7'	System	22 Nov 2020 17:25:00
User entered 'No (N)'	System	22 Nov 2020 17:25:00

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:13

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2020-11-22T12:24:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '86700494-dfcf-4921-8515-07dbdd0ee4a7'	System	22 Nov 2020 17:25:00
User entered 'No (N)'	System	22 Nov 2020 17:25:00

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-22T12:24:55', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '86700494-dfcf-4921-8515-07dbdd0ee4a7'	System	22 Nov 2020 17:25:00
User entered '22 Nov 2020 12:24:55'	System	22 Nov 2020 17:25:00

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:09:57

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929268

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929269

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929270

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929271

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929272

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929273

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929274

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929275

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929276

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929277

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929278

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929279

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929280

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929281

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929282

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929283

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929284

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929285

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929286

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929287

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929288

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929289

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929290

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929291

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929293

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929294

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929295

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929296

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929297

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929298

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929299

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929300

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929301

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929302

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929303

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929304

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929305

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929306

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929307

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929308

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929309

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929310

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929311

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929312

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929313

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:09:57

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929316

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929317

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929318

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929319

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929320

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929321

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929322

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929323

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929324

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929325

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929326

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929327

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929328

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929329

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929330

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929331

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929332

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929333

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929334

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929335

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929336

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929337

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929338

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929339

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929340

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929341

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929342

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929343

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929344

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929345

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929346

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929347

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929348

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929349

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929350

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929351

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929352

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929353

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929354

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929355

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929356

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929357

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929358

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929359

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929360

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929361

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929362

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929363

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929364

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929365

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929366

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929367

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929368

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929369

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929370

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929371

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929372

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929373

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929374

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929375

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929376

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929377

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929378

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929379

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929380

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929381

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929382

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929383

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929384

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929385

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929386

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929387

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929388

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929389

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929390

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929391

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929392

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929393

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929394

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929395

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929396

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929397

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929398

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929399

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929400

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929401

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929402

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929403

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929404

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929405

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929406

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929407

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929408

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929409

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929410

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929411

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929412

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929413

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929414

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929415

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929416

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929417

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929418

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929419

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929420

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929421

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929422

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929423

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929424

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929425

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929426

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929427

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929428

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929429

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929430

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929431

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929432

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929433

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929434

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929435

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929436

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929437

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929438

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929439

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929440

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929441

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929442

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929443

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929444

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929445

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929446

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929447

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929448

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929449

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929450

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929451

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929452

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929453

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929454

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929455

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929456

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929457

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929458

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929459

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929460

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929461

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929462

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929463

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929464

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929465

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929466

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929467

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929468

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929469

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929470

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929471

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929472

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929473

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929474

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929475

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929476

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929477

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929478

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929479

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929480

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929481

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929482

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929483

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929484

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929485

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929486

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929487

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929488

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929489

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929490

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929491

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929492

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929493

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929494

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929495

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929496

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929497

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929498

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929499

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929500

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929501

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929502

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929503

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929505

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929506

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929507

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929508

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929509

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929510

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929511

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929512

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929513

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929514

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929515

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929516

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929517

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929518

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929519

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929520

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929521

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929522

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929523

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929524

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929525

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929526

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929527

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929528

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929529

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929530

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929531

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929532

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929533

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929534

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929535

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929536

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929537

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929538

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929539

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929540

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929541

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929542

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929543

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929544

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929545

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929546

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929547

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929548

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929549

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929550

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929551

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929552

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929553

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929554

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929555

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929556

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929557

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929558

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929559

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929560

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929561

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929562

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929563

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929564

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929565

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929566

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929567

US3432202
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:27:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:09:57

FDA-CBER-2022-1614-5929568

US3432202
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 15:29:44

FDA-CBER-2022-1614-5929569

US3432202
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 15:29:44

FDA-CBER-2022-1614-5929570

US3432202
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Nov 2020 15:29:44

FDA-CBER-2022-1614-5929571

US3432202
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:27:13
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 15:29:44

FDA-CBER-2022-1614-5929572

US3432202
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 15:29:48

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US3432202
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:27:13
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 15:29:48

FDA-CBER-2022-1614-5929574

US3432202
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 26 Nov 2020 09:27:13
Did the participant experience any adverse events?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:30
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:27:03

FDA-CBER-2022-1614-5929575

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Adverse event

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location if Bilateral, Left, or Right. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:45:56
Query 'Per DM CLR: Please specify the location if Bilateral, Left, or Right. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'Will confirm which foot with the participant at next visit and update the AE and con Meds accordingly' (Site from DM).	Megan Powell (b) (4) (b) (4)	21 Oct 2020 22:58:31
User opened query 'Per DM CLR: Please specify the location if Bilateral, Left, or Right. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:33:21
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Foreign body, LLT: Foreign body - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 07:04:32
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 07:04:32
Data point term sent to Coder	System	27 Aug 2020 22:33:00
User entered 'Foreign Body in Foot'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929576

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Was this a medically-attended AE?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929577

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929578

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929579

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	17 Sep 2020 00:14:32
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	16 Sep 2020 20:03:26
User entered '20 Aug 2020'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929580

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User closed query 'Per CDM: Response noted; However per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. Exposure is recorded as 19-AUG-2020 at 15:39, and AE Start date is 20-AUG-2020. Please verify data and update AE Start time as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:12:57
Query 'Per CDM: Response noted; However per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. Exposure is recorded as 19-AUG-2020 at 15:39, and AE Start date is 20-AUG-2020. Please verify data and update AE Start time as appropriate. Thank you.' answered with 'unknown start time' (Site from DM).	Monica Feeley (b) (4) (b) (4)	21 Oct 2020 14:31:30
User opened query 'Per CDM: Response noted; However per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. Exposure is recorded as 19-AUG-2020 at 15:39, and AE Start date is 20-AUG-2020. Please verify data and update AE Start time as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 09:22:07
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 09:19:30
Query 'Data is required. Please provide.' answered with 'no start time, glass removal from foot' (Site from System).	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:33:14
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 22:32:46
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929581

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929582

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Sep 2020 21:43:49
User entered 'No (N)' reason for change: New Information	Phoebe Cunningham (b) (4)	02 Sep 2020 21:43:49
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Sep 2020 21:43:35
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929583

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '2 Sep 2020' reason for change: New Information	Phoebe Cunningham (b) (4)	02 Sep 2020 21:43:35
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929584

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 09:02:23
Query 'Data is required. Please provide.' answered with 'NA' (Site from System).	Phoebe Cunningham (b) (4)	02 Sep 2020 21:43:57
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 21:43:49
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929585

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929586

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Severity

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929587

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Is the adverse event serious?

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929588

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Death

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929589

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Life threatening

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929590

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929591

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929592

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929593

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Admitted to ICU?

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929594

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Number of Days in ICU

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929595

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929596

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929597

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Other medically important event

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929598

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Relationship to investigational product

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929599

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Relationship to Study Procedure

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929600

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Action taken with investigational product

Audit	User	Time (GMT)
User entered 'None (NONE)'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929601

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
None

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929602

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Concomitant Medication

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929603

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Concomitant Procedure

Audit	User	Time (GMT)
User entered '1'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929604

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Outcome

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Phoebe Cunningham (b) (4)	02 Sep 2020 21:43:35
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929606

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Narrative

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929607

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929608

US3432202
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:27:13
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 22:32:46

FDA-CBER-2022-1614-5929609

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
AEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:55:55
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:28
User entered 'USA-US078-2020-mRNA-1273-P301000003'	System	28 Sep 2020 12:53:24
User entered 'New'	(b) (4), (b) (6)	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5929610

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:31
User closed query 'Safety Medical Query: The subject was admitted to the hospital for confusion and dizziness secondary to uncontrolled hypertension. It appears, confusion was a symptom of uncontrolled hypertension. If correct, please consider updating event term to "Hypertensive urgency"' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:34:02
User closed query 'PV Query: Please provide the underlying cause of the confusion and consider updating the event term to the final diagnosis. If no etiology was determined, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:33:49
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Accelerated and malignant hypertension, PT: Hypertensive urgency, LLT: Hypertensive urgency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 12:33:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 12:33:52
Data point term sent to Coder	System	30 Oct 2020 12:33:08
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	30 Oct 2020 12:32:34
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	30 Oct 2020 12:32:34
User entered 'Hypertensive Urgency' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	30 Oct 2020 12:32:34
Query 'Safety Medical Query: The subject was admitted to the hospital for confusion and dizziness secondary to uncontrolled hypertension. It appears, confusion was a symptom of uncontrolled hypertension. If correct, please consider updating event term to "Hypertensive urgency"' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	30 Oct 2020 12:32:19
Query 'PV Query: Please provide the underlying cause of the confusion and consider updating the event term to the final diagnosis. If no etiology was determined, please state so.' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	30 Oct 2020 12:32:16
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:32:29

FDA-CBER-2022-1614-5929611

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Adverse event

Audit	User	Time (GMT)
User opened query 'Safety Medical Query: The subject was admitted to the hospital for confusion and dizziness secondary to uncontrolled hypertension. It appears, confusion was a symptom of uncontrolled hypertension. If correct, please consider updating event term to "Hypertensive urgency"' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:10:32
User opened query 'PV Query: Please provide the underlying cause of the confusion and consider updating the event term to the final diagnosis. If no etiology was determined, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:51:32
User coded data point as SOC: Psychiatric disorders, HLGT: Deliria (incl confusion), HLT: Confusion and disorientation, PT: Confusional state, LLT: Confusion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 22:13:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 22:13:54
Data point term sent to Coder	System	25 Sep 2020 22:12:34
User entered 'Confusion'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929612

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:00
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929613

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:01
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929614

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:04
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929615

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:06
User entered '25 Sep 2020'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929616

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:07
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929617

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929618

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:09
User entered 'No (N)' reason for change: New Information	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:26:48
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929619

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:11
User entered '30 Sep 2020' reason for change: New Information	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:26:48
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929620

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:14
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929621

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929622

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:16
User entered 'Grade 3/Severe (Grade 3/Severe)'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929623

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:17
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929624

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:21
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929625

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:22
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929626

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:24
User closed query 'Per CDM: Thank you for your response. Please update Hospital Discharge Date when known. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:36:51
Query 'Per CDM: Thank you for your response. Please update Hospital Discharge Date when known. ' answered with 'updated' (Site from DM).	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:21:00
User opened query 'Per CDM: Thank you for your response. Please update Hospital Discharge Date when known. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 18:41:38
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 18:41:04
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'was admitted 25SEP2020. not discharged and not admitted to ICU' (Site from System).	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:13:06
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	25 Sep 2020 22:12:24
User entered '1'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929627

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:26
User entered '25 Sep 2020'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

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US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:28
User entered '30 Sep 2020' reason for change: New Information	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:26:48
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929629

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:30
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

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US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:31
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

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US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:33
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

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US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:34
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929633

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:36
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

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US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:37
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

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US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:39
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

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US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:41
User closed query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 16 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 16:11:55
Query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 16 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 19:07:02
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 19:06:48
User opened query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 16 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:49:19
User entered 'None (NONE)'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929637

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:47
User entered '1'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

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US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:49
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929639

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:51
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

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US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:26:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

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US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:54
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929642

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Narrative

Audit	User	Time (GMT)
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)	11 Nov 2020 21:43:36
User closed query 'PV Query: Please confirm which statin medication the subject was taking (listed on CM eCRF).' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 21:43:32
Query 'PV Query: Please confirm which statin medication the subject was taking (listed on CM eCRF).' answered with 'udpated' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:22:19
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 'sent' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:21:09
User opened query 'PV Query: Please confirm which statin medication the subject was taking (listed on CM eCRF).' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 14:12:31
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)	09 Nov 2020 14:12:21
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:40
User closed query 'Per DM CLR: SAE Narrative indicates that the subject had a worsening of hypertension. However, there is no corresponding AE record that match this information. Please update to record the worsening event as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:50:09
User closed query 'Per DM CLR: Narrative contains a procedure. Please make sure that all procedures are recorded in the Con Proc eCRF. Update and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:50:04

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US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
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)	30 Oct 2020 19:33:33
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	30 Oct 2020 13:12:54
User entered 'PT RECEIVED SECOND VACCINE 16SEP2020. PATIENT WAS FOUND THIS MORNING WALKING OUTSIDE DISORIENTED BY A BYSTANDER WHO CALLED EMS. ALSO REPORTS DIZZINESS. WAS ADMITTED TODAY BECAUSE OF THE CONFUSION. HAD A CEREBRAL SCAN WITHOUT SIGNIFICANT CHANGES FROM PREVIOUS SCAN DONE IN 2019. HAD HTN IN THE ED (UP TO 204 SYSTOLIC) HE IS KNOWN WITH HTN, WHICH IS CAPTURED IN THE MEDICAL HISTORY. 02 OCT 2020- SAE DISCHARGE UPDATE: PT WAS HOSPITALIZED FROM 9/25 TO 9/30 FOR CONFUSION IN THE CONTEXT OF UNCONTROLLED HYPERTENSION. BP WAS CONTROLLED DURING HOSPITALIZATION WITH LISINOPRIL 5MG QD WHICH MUCH IMPROVEMENT. PT WAS BACK TO BASELINE AT DISCHARGE. 30OCT2020 updated: head CT (25SEP2020), chest XR (25SEP2020), brain MRI (25SEP2020), cervical spine MRI (28SEP2020) - all imaging showed no acute finding that can explain confusion. EEG (29SEP2020) - no epileptiform or lateralizing abnormalities LP (26SEP2020) - WBC count of 1, HSV PCR negative, Viral culture negative, bacteria culture negative' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	30 Oct 2020 13:12:54

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US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'head CT (25SEP2020), chest XR (25SEP2020), brain MRI (25SEP2020), cervical spine MRI (28SEP2020) - all imaging showed no acute finding that can explain confusion. EEG (29SEP2020) - no epileptiform or lateralizing abnormalities LP (26SEP2020) - WBC count of 1, HSV PCR negative, Viral culture negative, bacteria culture negative updates made to narrative as well as con procedures' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	30 Oct 2020 13:12:34
Query 'Per DM CLR: SAE Narrative indicates that the subject had a worsening of hypertension. However, there is no corresponding AE record that match this information. Please update to record the worsening event as appropriate. Otherwise, clarify.' answered with 'This AE is reflective of this' (Site from DM).	Monica Feeley (b) (4) (b) (4)	30 Oct 2020 12:32:47
User opened query 'Per DM CLR: SAE Narrative indicates that the subject had a worsening of hypertension. However, there is no corresponding AE record that match this information. Please update to record the worsening event as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:37:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:57:05
User closed query 'PV Query: It was reported the subject had known history of hypertension. Was the subject on antihypertensive therapy prior to study randomization? If so, please update ConMed eCRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 16:13:53
User closed query 'PV Query: Please confirm which statin medication the subject was taking (listed on CM eCRF).' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 16:13:42
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)	20 Oct 2020 16:13:30

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US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if hypertension is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If hypertension is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 16:13:16
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)	20 Oct 2020 16:12:51
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 'sending redacted summary ' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 19:17:07
Query 'Per DM CLR: Narrative contains a procedure. Please make sure that all procedures are recorded in the Con Proc eCRF. Update and reconcile as appropriate. ' answered with 'updated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 19:16:41
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 '25SEP2020- NP swab, negative' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 19:02:46
Query 'PV Query: Please confirm which statin medication the subject was taking (listed on CM eCRF).' answered with 'see ConMed form. Taking amlodipine JAN2020 - 25SEP2020. Lisinopril from 27SEP2020- current' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 18:52:53
Query 'PV Query: It was reported the subject had known history of hypertension. Was the subject on antihypertensive therapy prior to study randomization? If so, please update ConMed eCRF accordingly.' answered with 'added to ConMed' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 18:51:46

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US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if hypertension is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If hypertension is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' answered with 'we have updated to medical history. diagnosed JAN 2020' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 18:49:55
User opened query 'Per DM CLR: Narrative contains a procedure. Please make sure that all procedures are recorded in the Con Proc eCRF. Update and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 01:46:15
User opened query 'PV Query: Please confirm which statin medication the subject was taking (listed on CM eCRF).' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:10:06
Query 'PV Query: In addition to confusion, which is reported as the SAE, there is some mention of dizziness and BP at 204 mmHg systolic in this participant with history of hypertension. Please confirm if all SAE and leading diagnostic have been included in the EDC.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 14:42:33
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.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 14:42:25
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)	05 Oct 2020 13:53:20
User opened query 'PV Query: It was reported the subject had known history of hypertension. Was the subject on antihypertensive therapy prior to study randomization? If so, please update ConMed eCRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:52:26

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US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Narrative

Audit	User	Time (GMT)
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)	05 Oct 2020 13:51:18
User opened query 'PV Query: Please confirm if hypertension is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If hypertension is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:51:09
User opened query 'PV Query: In addition to confusion, which is reported as the SAE, there is some mention of dizziness and BP at 204 mmHg systolic in this participant with history of hypertension. Please confirm if all SAE and leading diagnostic have been included in the EDC.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:50:44
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)	05 Oct 2020 13:48:03
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)	05 Oct 2020 13:47:12

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US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Narrative

Audit	User	Time (GMT)
User entered 'PT RECEIVED SECOND VACCINE 16SEP2020. PATIENT WAS FOUND THIS MORNING WALKING OUTSIDE DISORIENTED BY A BYSTANDER WHO CALLED EMS. ALSO REPORTS DIZZINESS. WAS ADMITTED TODAY BECAUSE OF THE CONFUSION. HAD A CEREBRAL SCAN WITHOUT SIGNIFICANT CHANGES FROM PREVIOUS SCAN DONE IN 2019. HAD HTN IN THE ED (UP TO 204 SYSTOLIC) HE IS KNOWN WITH HTN, WHICH IS CAPTURED IN THE MEDICAL HISTORY. 02 OCT 2020- SAE DISCHARGE UPDATE: Pt was hospitalized from 9/25 to 9/30 for confusion in the context of uncontrolled hypertension. BP was controlled during hospitalization with lisinopril 5mg QD which much improvement. Pt was back to baseline at discharge.' reason for change: New Information	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:26:48
User entered 'Pt received second vaccine 16SEP2020. Patient was found this morning walking outside disoriented by a bystander who called EMS. Also reports dizziness. Was admitted today because of the confusion. Had a cerebral scan without significant changes from previous scan done in 2019. Had HTN in the ED (up to 204 Systolic) He is known with HTN, which is captured in the medical history.'	Xhoi Mitre (b) (4) (b) (4)	25 Sep 2020 22:12:24

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US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 22:12:24

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US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929651

US3432202
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:27:13
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	25 Sep 2020 22:12:24

FDA-CBER-2022-1614-5929652

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 23:33:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 23:33:44
Data point term sent to Coder	System	02 Oct 2020 23:32:29
User entered 'Dizziness'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Was this a medically-attended AE?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

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US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

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US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

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US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929657

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

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US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929659

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

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US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

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US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

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US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929663

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Severity

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929664

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Is the adverse event serious?

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929665

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Death

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929666

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Life threatening

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929667

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929668

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929669

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929670

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Admitted to ICU?

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929671

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Number of Days in ICU

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929672

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929673

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929674

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Other medically important event

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929675

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Relationship to investigational product

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929676

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Relationship to Study Procedure

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929677

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929678

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Oct 2020 23:32:08
User entered '1' reason for change: Data Entry Error	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:08
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Oct 2020 23:32:00
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929679

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Concomitant Medication

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929680

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Concomitant Procedure

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929681

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Outcome

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929682

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929683

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Narrative

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929684

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929685

US3432202
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:27:13
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 23:32:00

FDA-CBER-2022-1614-5929686

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:27:13

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

Audit	User	Time (GMT)
User opened query 'Per CDM: Diary dose 2 temperature day log #1, #2 indicates medication was taken for Pain / Fever. However there is no medication recorded for the corresponding dates. Please review and update as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:37:48
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:32:49
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:58:36

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIBENCLAMIDE, PRODUCTSYNONYM: GLYBURIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:01:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:01:05
Data point term sent to Coder	System	19 Aug 2020 21:00:36
User entered 'glyburide'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:00:13

FDA-CBER-2022-1614-5929688

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:00:13

FDA-CBER-2022-1614-5929689

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered 'diabetes mellitus'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:00:13

FDA-CBER-2022-1614-5929690

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered 'unk'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:00:13

FDA-CBER-2022-1614-5929691

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Per CDM: Per query response, please select ‘Other’ from the drop down and mention ‘Unknown’ in the ‘If dose unit is Other, specify’ box. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 10:24:31
Query 'Per CDM: Per query response, please select ‘Other’ from the drop down and mention ‘Unknown’ in the ‘If dose unit is Other, specify’ box. Thank you.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:01:45
Un-reviewed for Data Management.	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:00:57
User entered 'Other (OTHER)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:00:57
User opened query 'Per CDM: Per query response, please select ‘Other’ from the drop down and mention ‘Unknown’ in the ‘If dose unit is Other, specify’ box. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 18:01:27
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 17:19:12
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:00:25
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:00:13
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:00:13

FDA-CBER-2022-1614-5929692

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Un-reviewed for Data Management.	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:00:57
User entered 'unknown' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:00:57
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:00:13

FDA-CBER-2022-1614-5929693

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered 'unknown (UNKNOWN)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:00:13

FDA-CBER-2022-1614-5929694

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:00:13

FDA-CBER-2022-1614-5929695

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered 'Oral (ORAL)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:00:13

FDA-CBER-2022-1614-5929696

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:00:13

FDA-CBER-2022-1614-5929697

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:00:13

FDA-CBER-2022-1614-5929698

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered '1'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:00:13

FDA-CBER-2022-1614-5929699

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:00:13

FDA-CBER-2022-1614-5929700

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:00:13

FDA-CBER-2022-1614-5929701

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:00:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 21:00:32
User entered 'No (N)' reason for change: Data Entry Error	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:00:32
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:00:13
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:00:13

FDA-CBER-2022-1614-5929702

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:00:13

FDA-CBER-2022-1614-5929703

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:00:13

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:00:13

FDA-CBER-2022-1614-5929705

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:31:14
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:30:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:04:49
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:04:49
Data point term sent to Coder	System	26 Aug 2020 12:50:45
User entered 'lorazepam'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:49:47

FDA-CBER-2022-1614-5929706

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:31:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:30:07
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:49:47

FDA-CBER-2022-1614-5929707

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:31:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:30:09
User entered 'Anxeity'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:49:47

FDA-CBER-2022-1614-5929708

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:08:14
User entered '0.5' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:08:14
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:31:08
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:30:11
User entered 'UNK'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:49:47

FDA-CBER-2022-1614-5929709

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:08:14
User entered 'mg (mg)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:08:14
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Other (OTHER)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:49:47

FDA-CBER-2022-1614-5929710

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:08:14
User entered empty; reason for change Data Entry Error	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:08:14
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Unknown'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:49:47

FDA-CBER-2022-1614-5929711

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 12:50:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 12:50:03
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:50:03
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 12:49:47
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:49:47

FDA-CBER-2022-1614-5929712

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:49:47

FDA-CBER-2022-1614-5929713

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:49:47

FDA-CBER-2022-1614-5929714

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:49:47

FDA-CBER-2022-1614-5929715

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:49:47

FDA-CBER-2022-1614-5929716

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '1'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:49:47

FDA-CBER-2022-1614-5929717

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:49:47

FDA-CBER-2022-1614-5929718

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:49:47

FDA-CBER-2022-1614-5929719

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:49:47

FDA-CBER-2022-1614-5929720

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 12:49:47

FDA-CBER-2022-1614-5929721

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 12:49:47

FDA-CBER-2022-1614-5929722

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 12:49:47

FDA-CBER-2022-1614-5929723

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:02:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:02:06
Data point term sent to Coder	System	19 Aug 2020 21:01:38
User entered 'Glipizide'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:01:28

FDA-CBER-2022-1614-5929724

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:01:28

FDA-CBER-2022-1614-5929725

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'diabetes mellitus'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:01:28

FDA-CBER-2022-1614-5929726

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unk'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:01:28

FDA-CBER-2022-1614-5929727

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 10:24:42
Query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:02:29
User entered 'Other (OTHER)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:02:20
User opened query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 18:02:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 17:21:57
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:01:38
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:01:28
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:01:28

FDA-CBER-2022-1614-5929728

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unknown' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:02:20
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:01:28

FDA-CBER-2022-1614-5929729

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unknown (UNKNOWN)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:01:28

FDA-CBER-2022-1614-5929730

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:01:28

FDA-CBER-2022-1614-5929731

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:01:28

FDA-CBER-2022-1614-5929732

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:01:28

FDA-CBER-2022-1614-5929733

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:01:28

FDA-CBER-2022-1614-5929734

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '1'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:01:28

FDA-CBER-2022-1614-5929735

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:01:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 21:01:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:01:44
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:01:28
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:01:28

FDA-CBER-2022-1614-5929736

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:01:28

FDA-CBER-2022-1614-5929737

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:01:28

FDA-CBER-2022-1614-5929738

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:01:28

FDA-CBER-2022-1614-5929739

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:01:28

FDA-CBER-2022-1614-5929740

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:01:28

FDA-CBER-2022-1614-5929741

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: FLUOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PROZAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:03:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:03:06
Data point term sent to Coder	System	19 Aug 2020 21:02:38
User entered 'Prozac'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:18

FDA-CBER-2022-1614-5929742

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:18

FDA-CBER-2022-1614-5929743

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Anxiety'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:18

FDA-CBER-2022-1614-5929744

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unk'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:18

FDA-CBER-2022-1614-5929745

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Per CDM: Per query response, please select ‘Other’ from the drop down and mention ‘Unknown’ in the ‘If dose unit is Other, specify’ box. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 10:24:46
Query 'Per CDM: Per query response, please select ‘Other’ from the drop down and mention ‘Unknown’ in the ‘If dose unit is Other, specify’ box. Thank you.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:03:39
User entered 'Other (OTHER)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:03:27
User opened query 'Per CDM: Per query response, please select ‘Other’ from the drop down and mention ‘Unknown’ in the ‘If dose unit is Other, specify’ box. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 18:03:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 17:22:08
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:02:18
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:18

FDA-CBER-2022-1614-5929746

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Unknown' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:03:27
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:18

FDA-CBER-2022-1614-5929747

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unknown (UNKNOWN)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:18

FDA-CBER-2022-1614-5929748

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:18

FDA-CBER-2022-1614-5929749

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:18

FDA-CBER-2022-1614-5929750

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:18

FDA-CBER-2022-1614-5929751

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:18

FDA-CBER-2022-1614-5929752

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '1'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:18

FDA-CBER-2022-1614-5929753

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:18

FDA-CBER-2022-1614-5929754

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:18

FDA-CBER-2022-1614-5929755

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:18

FDA-CBER-2022-1614-5929756

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:02:18

FDA-CBER-2022-1614-5929757

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:02:18

FDA-CBER-2022-1614-5929758

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:02:18

FDA-CBER-2022-1614-5929759

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:24:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:24:43
Data point term sent to Coder	System	10 Nov 2020 22:23:25
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:23:01
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:23:01
User entered 'SIMVASTATIN' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: HMG COA REDUCTASE INHIBITORS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 05:02:45
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 05:02:45
Data point term sent to Coder	System	07 Sep 2020 21:52:55
User closed query 'CDM-Coding: The trade name STATIN can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' (Site from System).	System	07 Sep 2020 21:52:35
Query 'CDM-Coding: The trade name STATIN can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' answered with 'specific statin not specified ' (Site from System).	Monica Feeley (b) (4) (b) (4)	07 Sep 2020 21:52:35

FDA-CBER-2022-1614-5929760

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:13

Name of Medication

Audit	User	Time (GMT)
User opened query 'CDM-Coding: The trade name STATIN can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' (Site from System).	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:49:45
User closed query 'Please specify the name of Statin.' (Site from CRA).	(b) (4), (b) (6)	27 Aug 2020 16:27:40
Query 'Please specify the name of Statin.' answered with 'statin name not specified by participant' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:51:41
User opened query 'Please specify the name of Statin.' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 20:26:13
Data point term sent to Coder	System	19 Aug 2020 21:03:40
User entered 'Statin'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:55

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:55

FDA-CBER-2022-1614-5929762

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'High cholesterol'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:55

FDA-CBER-2022-1614-5929763

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unk'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:55

FDA-CBER-2022-1614-5929764

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Per CDM: Per query response, please select ‘Other’ from the drop down and mention ‘Unknown’ in the ‘If dose unit is Other, specify’ box. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 10:24:52
Query 'Per CDM: Per query response, please select ‘Other’ from the drop down and mention ‘Unknown’ in the ‘If dose unit is Other, specify’ box. Thank you.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:04:17
User entered 'Other (OTHER)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:04:09
User opened query 'Per CDM: Per query response, please select ‘Other’ from the drop down and mention ‘Unknown’ in the ‘If dose unit is Other, specify’ box. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 18:03:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 17:22:16
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:52
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:02:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:55

FDA-CBER-2022-1614-5929765

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Unknown' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:04:09
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:55

FDA-CBER-2022-1614-5929766

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unknown (UNKNOWN)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:55

FDA-CBER-2022-1614-5929767

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:55

FDA-CBER-2022-1614-5929768

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:55

FDA-CBER-2022-1614-5929769

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:55

FDA-CBER-2022-1614-5929770

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:55

FDA-CBER-2022-1614-5929771

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '1'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:55

FDA-CBER-2022-1614-5929772

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:55

FDA-CBER-2022-1614-5929773

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:55

FDA-CBER-2022-1614-5929774

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:02:55

FDA-CBER-2022-1614-5929775

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:02:55

FDA-CBER-2022-1614-5929776

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:02:55

FDA-CBER-2022-1614-5929777

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:02:55

FDA-CBER-2022-1614-5929778

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:35:17
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:35:17
Data point term sent to Coder	System	19 Aug 2020 21:04:41
User entered 'Pantoprazole'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:03:51

FDA-CBER-2022-1614-5929779

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:03:51

FDA-CBER-2022-1614-5929780

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'duodenal ulcer'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:03:51

FDA-CBER-2022-1614-5929781

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unk'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:03:51

FDA-CBER-2022-1614-5929782

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Per CDM: Per query response, please select ‘Other’ from the drop down and mention ‘Unknown’ in the ‘If dose unit is Other, specify’ box. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 10:24:57
Query 'Per CDM: Per query response, please select ‘Other’ from the drop down and mention ‘Unknown’ in the ‘If dose unit is Other, specify’ box. Thank you.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:04:58
User entered 'Other (OTHER)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:04:51
User opened query 'Per CDM: Per query response, please select ‘Other’ from the drop down and mention ‘Unknown’ in the ‘If dose unit is Other, specify’ box. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 18:04:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 17:22:27
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:49
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:03:51
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:03:51

FDA-CBER-2022-1614-5929783

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Unknown' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:04:51
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:03:51

FDA-CBER-2022-1614-5929784

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unknown (UNKNOWN)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:03:51

FDA-CBER-2022-1614-5929785

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:03:51

FDA-CBER-2022-1614-5929786

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:03:51

FDA-CBER-2022-1614-5929787

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:03:51

FDA-CBER-2022-1614-5929788

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:03:51

FDA-CBER-2022-1614-5929789

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '1'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:03:51

FDA-CBER-2022-1614-5929790

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:03:51

FDA-CBER-2022-1614-5929791

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:03:51

FDA-CBER-2022-1614-5929792

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:03:51

FDA-CBER-2022-1614-5929793

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:03:51

FDA-CBER-2022-1614-5929794

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:03:51

FDA-CBER-2022-1614-5929795

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:03:51

FDA-CBER-2022-1614-5929796

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Please specify name of NSAIDS' (Site from CRA).	(b) (4), (b) (6)	27 Aug 2020 16:27:59
Query 'Please specify name of NSAIDS' answered with 'NSAID name not specified by participant ' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 12:51:23
User opened query 'Please specify name of NSAIDS' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 20:40:41
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, PRODUCT: NSAIDS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:48:16
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:48:16
Data point term sent to Coder	System	19 Aug 2020 21:04:42
User entered 'NSAIDS'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:22

FDA-CBER-2022-1614-5929797

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:22

FDA-CBER-2022-1614-5929798

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:48:03
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'see medical history for "daily headaches"' (Site from DM).	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 18:50:55
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 09:02:07
User entered 'headache'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:22

FDA-CBER-2022-1614-5929799

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unk'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:22

FDA-CBER-2022-1614-5929800

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Per CDM: Per query response, please select ‘Other’ from the drop down and mention ‘Unknown’ in the ‘If dose unit is Other, specify’ box. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 10:25:03
Query 'Per CDM: Per query response, please select ‘Other’ from the drop down and mention ‘Unknown’ in the ‘If dose unit is Other, specify’ box. Thank you.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:05:52
User entered 'Other (OTHER)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:05:41
User opened query 'Per CDM: Per query response, please select ‘Other’ from the drop down and mention ‘Unknown’ in the ‘If dose unit is Other, specify’ box. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 18:04:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 17:22:35
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:36
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:04:22
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:22

FDA-CBER-2022-1614-5929801

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unknown' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:05:41
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:22

FDA-CBER-2022-1614-5929802

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'as needed (PRN)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:22

FDA-CBER-2022-1614-5929803

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:22

FDA-CBER-2022-1614-5929804

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:22

FDA-CBER-2022-1614-5929805

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:22

FDA-CBER-2022-1614-5929806

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	19 Aug 2020 21:04:38
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	19 Aug 2020 21:04:22
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:22

FDA-CBER-2022-1614-5929807

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '1' reason for change: Data Entry Error	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:38
User entered '0'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:22

FDA-CBER-2022-1614-5929808

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:22

FDA-CBER-2022-1614-5929809

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:22

FDA-CBER-2022-1614-5929810

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 21:04:22

FDA-CBER-2022-1614-5929811

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:04:22

FDA-CBER-2022-1614-5929812

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:04:22

FDA-CBER-2022-1614-5929813

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:04:22

FDA-CBER-2022-1614-5929814

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
User closed query 'please add to source con-med log' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:43:13
Query 'please add to source con-med log' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:24:14
User opened query 'please add to source con-med log' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 19:39:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:49:34
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:49:34
Data point term sent to Coder	System	21 Oct 2020 23:00:22
Coding entries removed.	Megan Powell (b) (4) (b) (4)	21 Oct 2020 23:00:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:54:31
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:54:31
Data point term sent to Coder	System	27 Aug 2020 13:36:00
Data point term sent to Coder	System	26 Aug 2020 21:59:04
User entered 'Ibuprofen'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

FDA-CBER-2022-1614-5929815

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

FDA-CBER-2022-1614-5929816

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Per DM CLR: Please review and confirm if this indiction pertains to the AE condition of 'FOREIGN BODY IN FOOT'. If yes, please update verbatim for consistency. Please reconcile with AE eCRF and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:17:46
User closed query 'Per DM CLR: Please confirm if this Lesion is benign or malignant; Please update to include the location of the lesion (e.g. left, right or bilateral). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:48:52
Query 'Per DM CLR: Please review and confirm if this indiction pertains to the AE condition of 'FOREIGN BODY IN FOOT'. If yes, please update verbatim for consistency. Please reconcile with AE eCRF and update as appropriate.' answered with 'Yes, has been updated' (Site from DM).	Megan Powell (b) (4) (b) (4)	21 Oct 2020 23:00:34
Query 'Per DM CLR: Please confirm if this Lesion is benign or malignant; Please update to include the location of the lesion (e.g. left, right or bilateral). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'Benign' (Site from DM).	Megan Powell (b) (4) (b) (4)	21 Oct 2020 23:00:22
User entered 'Foreign Body in Foot' reason for change: Data Entry Error	Megan Powell (b) (4) (b) (4)	21 Oct 2020 23:00:16
User opened query 'Per DM CLR: Please review and confirm if this indiction pertains to the AE condition of 'FOREIGN BODY IN FOOT'. If yes, please update verbatim for consistency. Please reconcile with AE eCRF and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 09:01:56
User opened query 'Per DM CLR: Please confirm if this Lesion is benign or malignant; Please update to include the location of the lesion (e.g. left, right or bilateral). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 09:01:47

FDA-CBER-2022-1614-5929817

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
User entered 'foot lesions'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

FDA-CBER-2022-1614-5929818

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '200'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

FDA-CBER-2022-1614-5929819

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'mg (mg)'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

FDA-CBER-2022-1614-5929820

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

FDA-CBER-2022-1614-5929821

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'as needed (PRN)'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

FDA-CBER-2022-1614-5929822

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

FDA-CBER-2022-1614-5929823

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 13:35:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 13:35:23
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	27 Aug 2020 13:35:23
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 21:58:07
User entered empty.	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

FDA-CBER-2022-1614-5929824

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

FDA-CBER-2022-1614-5929825

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '21 Aug 2020'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

FDA-CBER-2022-1614-5929826

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '0'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

FDA-CBER-2022-1614-5929827

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

FDA-CBER-2022-1614-5929828

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '1 Sep 2020' reason for change: New Information	Phoebe Cunningham (b) (4)	02 Sep 2020 21:42:11
User entered '22 Aug 2020'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

FDA-CBER-2022-1614-5929829

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

FDA-CBER-2022-1614-5929830

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 21:58:07

FDA-CBER-2022-1614-5929831

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 21:58:07

FDA-CBER-2022-1614-5929832

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 21:58:07

FDA-CBER-2022-1614-5929833

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 23:30:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 23:30:56
Data point term sent to Coder	System	02 Oct 2020 23:30:28
User entered 'Amlodipine'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:29:27

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:29:27

FDA-CBER-2022-1614-5929835

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'HTN'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:29:27

FDA-CBER-2022-1614-5929836

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '5'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:29:27

FDA-CBER-2022-1614-5929837

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'mg (mg)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:29:27

FDA-CBER-2022-1614-5929838

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:29:27

FDA-CBER-2022-1614-5929839

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'once daily (QD)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:29:27

FDA-CBER-2022-1614-5929840

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:29:27

FDA-CBER-2022-1614-5929841

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:29:27

FDA-CBER-2022-1614-5929842

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:29:27

FDA-CBER-2022-1614-5929843

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'UN Jan 2020'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:29:27

FDA-CBER-2022-1614-5929844

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:29:27

FDA-CBER-2022-1614-5929845

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:29:27

FDA-CBER-2022-1614-5929846

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:29:27

FDA-CBER-2022-1614-5929847

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:29:27

FDA-CBER-2022-1614-5929848

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 23:29:27

FDA-CBER-2022-1614-5929849

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 23:29:27

FDA-CBER-2022-1614-5929850

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 23:29:27

FDA-CBER-2022-1614-5929851

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:43:48
User closed query 'Please revise spelling to Lisinopril' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:43:47
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)	10 Nov 2020 22:27:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:27:45
Data point term sent to Coder	System	10 Nov 2020 22:26:27
Query 'Please revise spelling to Lisinopril' answered by data change (Site from CRA).	System	10 Nov 2020 22:25:34
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:25:34
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:25:34
User entered 'LISINOPRIL' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:25:34
User opened query 'Please revise spelling to Lisinopril' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 20:00:13
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
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)	03 Oct 2020 06:58:42
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 06:58:42
Data point term sent to Coder	System	02 Oct 2020 23:30:26
User entered 'Lisonpril'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:30:17

FDA-CBER-2022-1614-5929852

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:30:17

FDA-CBER-2022-1614-5929853

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'HTN'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:30:17

FDA-CBER-2022-1614-5929854

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '5'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:30:17

FDA-CBER-2022-1614-5929855

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'mg (mg)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:30:17

FDA-CBER-2022-1614-5929856

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:30:17

FDA-CBER-2022-1614-5929857

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'once daily (QD)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:30:17

FDA-CBER-2022-1614-5929858

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:30:17

FDA-CBER-2022-1614-5929859

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:30:17

FDA-CBER-2022-1614-5929860

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:30:17

FDA-CBER-2022-1614-5929861

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '27 Sep 2020'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:30:17

FDA-CBER-2022-1614-5929862

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:30:17

FDA-CBER-2022-1614-5929863

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:30:17

FDA-CBER-2022-1614-5929864

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:30:17

FDA-CBER-2022-1614-5929865

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	02 Oct 2020 23:30:17

FDA-CBER-2022-1614-5929866

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 23:30:17

FDA-CBER-2022-1614-5929867

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 23:30:17

FDA-CBER-2022-1614-5929868

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 23:30:17

FDA-CBER-2022-1614-5929869

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:27:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:27:46
Data point term sent to Coder	System	10 Nov 2020 22:27:27
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:27:08
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:48:22
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:48:22
Data point term sent to Coder	System	06 Nov 2020 15:40:02
User entered 'Labetalol'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:14

FDA-CBER-2022-1614-5929870

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:14

FDA-CBER-2022-1614-5929871

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:44:27
User closed query 'Please change spelling to HYPERTENSION' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:44:26
Query 'Please change spelling to HYPERTENSION' answered by data change (Site from CRA).	System	10 Nov 2020 22:27:08
User entered 'HYPERTENSION' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:27:08
User opened query 'Please change spelling to HYPERTENSION' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 19:55:43
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 19:55:21
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Hpyertension'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:14

FDA-CBER-2022-1614-5929872

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '200'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:14

FDA-CBER-2022-1614-5929873

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:14

FDA-CBER-2022-1614-5929874

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:14

FDA-CBER-2022-1614-5929875

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'once (ONCE)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:14

FDA-CBER-2022-1614-5929876

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:14

FDA-CBER-2022-1614-5929877

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:14

FDA-CBER-2022-1614-5929878

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:14

FDA-CBER-2022-1614-5929879

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:14

FDA-CBER-2022-1614-5929880

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '0'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:14

FDA-CBER-2022-1614-5929881

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:14

FDA-CBER-2022-1614-5929882

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:14

FDA-CBER-2022-1614-5929883

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:14

FDA-CBER-2022-1614-5929884

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:39:14

FDA-CBER-2022-1614-5929885

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:39:14

FDA-CBER-2022-1614-5929886

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:39:14

FDA-CBER-2022-1614-5929887

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 16:20:18
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 16:20:18
Data point term sent to Coder	System	06 Nov 2020 15:40:03
User entered 'Labetalol'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:45

FDA-CBER-2022-1614-5929888

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:45

FDA-CBER-2022-1614-5929889

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Hypertension'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:45

FDA-CBER-2022-1614-5929890

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '10'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:45

FDA-CBER-2022-1614-5929891

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:45

FDA-CBER-2022-1614-5929892

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:45

FDA-CBER-2022-1614-5929893

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'other (OTHER)' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:42:58
User entered 'once (ONCE)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:45

FDA-CBER-2022-1614-5929894

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Twice' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:42:58
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:45

FDA-CBER-2022-1614-5929895

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:45

FDA-CBER-2022-1614-5929896

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:45

FDA-CBER-2022-1614-5929897

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:45

FDA-CBER-2022-1614-5929898

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '0'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:45

FDA-CBER-2022-1614-5929899

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:45

FDA-CBER-2022-1614-5929900

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:45

FDA-CBER-2022-1614-5929901

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:45

FDA-CBER-2022-1614-5929902

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:39:45

FDA-CBER-2022-1614-5929903

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:39:45

FDA-CBER-2022-1614-5929904

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:39:45

FDA-CBER-2022-1614-5929905

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:48:22
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:48:22
Data point term sent to Coder	System	06 Nov 2020 15:41:05
User entered 'Labetalol'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:12

FDA-CBER-2022-1614-5929906

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:12

FDA-CBER-2022-1614-5929907

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Hypertension'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:12

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '20'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:12

FDA-CBER-2022-1614-5929909

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:12

FDA-CBER-2022-1614-5929910

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:12

FDA-CBER-2022-1614-5929911

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'once (ONCE)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:12

FDA-CBER-2022-1614-5929912

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:12

FDA-CBER-2022-1614-5929913

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:12

FDA-CBER-2022-1614-5929914

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:12

FDA-CBER-2022-1614-5929915

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:12

FDA-CBER-2022-1614-5929916

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '0'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:12

FDA-CBER-2022-1614-5929917

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:12

FDA-CBER-2022-1614-5929918

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:12

FDA-CBER-2022-1614-5929919

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:12

FDA-CBER-2022-1614-5929920

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:40:12

FDA-CBER-2022-1614-5929921

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:40:12

FDA-CBER-2022-1614-5929922

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:40:12

FDA-CBER-2022-1614-5929923

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:44:52
User closed query 'This medication is not listed in the discharge summary, please verify if it was given to subject, edit as required.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:44:50
Query 'This medication is not listed in the discharge summary, please verify if it was given to subject, edit as required.' answered with 'it is listed in discharge summary' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:31:56
User opened query 'This medication is not listed in the discharge summary, please verify if it was given to subject, edit as required.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 20:16:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 20:14:56
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:47:19
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:47:19
Data point term sent to Coder	System	06 Nov 2020 15:41:07
User entered 'Hydralazine'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:46

FDA-CBER-2022-1614-5929924

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:46

FDA-CBER-2022-1614-5929925

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Hypertension'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:46

FDA-CBER-2022-1614-5929926

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '10'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:46

FDA-CBER-2022-1614-5929927

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:46

FDA-CBER-2022-1614-5929928

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:46

FDA-CBER-2022-1614-5929929

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'once (ONCE)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:46

FDA-CBER-2022-1614-5929930

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:46

FDA-CBER-2022-1614-5929931

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:46

FDA-CBER-2022-1614-5929932

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:46

FDA-CBER-2022-1614-5929933

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:46

FDA-CBER-2022-1614-5929934

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '0'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:46

FDA-CBER-2022-1614-5929935

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:46

FDA-CBER-2022-1614-5929936

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:46

FDA-CBER-2022-1614-5929937

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:46

FDA-CBER-2022-1614-5929938

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:40:46

FDA-CBER-2022-1614-5929939

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:40:46

FDA-CBER-2022-1614-5929940

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:40:46

FDA-CBER-2022-1614-5929941

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:05:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:05:12
Data point term sent to Coder	System	20 Nov 2020 21:04:53
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:04:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
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)	06 Nov 2020 15:42:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:42:34
Data point term sent to Coder	System	06 Nov 2020 15:42:08
User entered 'Tylenol'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:15

FDA-CBER-2022-1614-5929942

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:15

FDA-CBER-2022-1614-5929943

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:04:37
User entered 'Mild pain in hospital' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:04:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:45:18
User closed query 'Please check if Indication is correct, edit in source con-med log & EDC.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:45:17
Query 'Please check if Indication is correct, edit in source con-med log & EDC.' answered with 'this is correct.' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:32:38
User opened query 'Please check if Indication is correct, edit in source con-med log & EDC.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 19:57:06
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 19:56:35
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Hypertension'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:15

FDA-CBER-2022-1614-5929944

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '1000'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:15

FDA-CBER-2022-1614-5929945

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:15

FDA-CBER-2022-1614-5929946

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:15

FDA-CBER-2022-1614-5929947

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'once (ONCE)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:15

FDA-CBER-2022-1614-5929948

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:15

FDA-CBER-2022-1614-5929949

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:15

FDA-CBER-2022-1614-5929950

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:15

FDA-CBER-2022-1614-5929951

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:15

FDA-CBER-2022-1614-5929952

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '0'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:15

FDA-CBER-2022-1614-5929953

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:15

FDA-CBER-2022-1614-5929954

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:15

FDA-CBER-2022-1614-5929955

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:15

FDA-CBER-2022-1614-5929956

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:41:15

FDA-CBER-2022-1614-5929957

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:41:15

FDA-CBER-2022-1614-5929958

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:41:15

FDA-CBER-2022-1614-5929959

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:45:49
User closed query 'please check if this medication was given to subject as subject was already on Lisinopril 5mg by 30Sep20.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:45:47
Query 'please check if this medication was given to subject as subject was already on Lisinopril 5mg by 30Sep20.' answered with 'this is what notes said' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:36:28
User opened query 'please check if this medication was given to subject as subject was already on Lisinopril 5mg by 30Sep20.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 20:22:36
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 20:21:38
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
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)	06 Nov 2020 15:58:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:58:19
Data point term sent to Coder	System	06 Nov 2020 15:42:08
User entered 'Lisinopril'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:42

FDA-CBER-2022-1614-5929960

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:42

FDA-CBER-2022-1614-5929961

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Hypertension'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:42

FDA-CBER-2022-1614-5929962

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '2.5'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:42

FDA-CBER-2022-1614-5929963

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:42

FDA-CBER-2022-1614-5929964

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:42

FDA-CBER-2022-1614-5929965

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 20:59:31
User entered 'once daily (QD)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 20:59:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'once (ONCE)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:42

FDA-CBER-2022-1614-5929966

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:42

FDA-CBER-2022-1614-5929967

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:42

FDA-CBER-2022-1614-5929968

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:42

FDA-CBER-2022-1614-5929969

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '30 Sep 2020'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:42

FDA-CBER-2022-1614-5929970

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '0'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:42

FDA-CBER-2022-1614-5929971

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:42

FDA-CBER-2022-1614-5929972

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '30 Sep 2020'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:42

FDA-CBER-2022-1614-5929973

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:42

FDA-CBER-2022-1614-5929974

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 20:59:31
User entered empty.	System	06 Nov 2020 15:41:42

FDA-CBER-2022-1614-5929975

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 20:59:31
User entered empty.	System	06 Nov 2020 15:41:42

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 20:59:31
User entered empty.	System	06 Nov 2020 15:41:42

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:42
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:42
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
Data point term sent to Coder	System	20 Nov 2020 21:00:44
User entered 'Ibuprofen'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:00:42

FDA-CBER-2022-1614-5929978

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:00:42

FDA-CBER-2022-1614-5929979

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'mild pain while in hospital'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:00:42

FDA-CBER-2022-1614-5929980

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '400'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:00:42

FDA-CBER-2022-1614-5929981

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:00:42

FDA-CBER-2022-1614-5929982

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:00:42

FDA-CBER-2022-1614-5929983

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'as needed (PRN)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:00:42

FDA-CBER-2022-1614-5929984

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:00:42

FDA-CBER-2022-1614-5929985

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:00:42

FDA-CBER-2022-1614-5929986

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:00:42

FDA-CBER-2022-1614-5929987

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '28 Sep 2020'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:00:42

FDA-CBER-2022-1614-5929988

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '0'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:00:42

FDA-CBER-2022-1614-5929989

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:00:42

FDA-CBER-2022-1614-5929990

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '30 Sep 2020'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:00:42

FDA-CBER-2022-1614-5929991

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:00:42

FDA-CBER-2022-1614-5929992

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:00:42

FDA-CBER-2022-1614-5929993

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:00:42

FDA-CBER-2022-1614-5929994

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:00:42

FDA-CBER-2022-1614-5929995

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:03:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:03:04
Data point term sent to Coder	System	20 Nov 2020 21:01:45
User entered 'Senokot'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:01:38

FDA-CBER-2022-1614-5929996

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:01:38

FDA-CBER-2022-1614-5929997

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'mild constipation'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:01:38

FDA-CBER-2022-1614-5929998

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '2'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:01:38

FDA-CBER-2022-1614-5929999

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'tablet (TABLET)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:01:38

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:01:38

FDA-CBER-2022-1614-5930001

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'twice daily (BID)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:01:38

FDA-CBER-2022-1614-5930002

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:01:38

FDA-CBER-2022-1614-5930003

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:01:38

FDA-CBER-2022-1614-5930004

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:01:38

FDA-CBER-2022-1614-5930005

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '26 Sep 2020'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:01:38

FDA-CBER-2022-1614-5930006

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '0'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:01:38

FDA-CBER-2022-1614-5930007

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:01:38

FDA-CBER-2022-1614-5930008

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '30 Sep 2020'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:01:38

FDA-CBER-2022-1614-5930009

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:01:38

FDA-CBER-2022-1614-5930010

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	20 Nov 2020 21:01:38

FDA-CBER-2022-1614-5930011

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 21:01:38

FDA-CBER-2022-1614-5930012

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 21:01:38

FDA-CBER-2022-1614-5930013

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:47
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
Data point term sent to Coder	System	20 Nov 2020 21:02:49
User entered 'Lovenox'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:02:29

FDA-CBER-2022-1614-5930014

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:02:29

FDA-CBER-2022-1614-5930015

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'blood clot prevention'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:02:29

FDA-CBER-2022-1614-5930016

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '40'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:02:29

FDA-CBER-2022-1614-5930017

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:02:29

FDA-CBER-2022-1614-5930018

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:02:29

FDA-CBER-2022-1614-5930019

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'once daily (QD)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:02:29

FDA-CBER-2022-1614-5930020

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:02:29

FDA-CBER-2022-1614-5930021

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Subcutaneous (SUBCUTANEOUS)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:02:29

FDA-CBER-2022-1614-5930022

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:02:29

FDA-CBER-2022-1614-5930023

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '28 Sep 2020'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:02:29

FDA-CBER-2022-1614-5930024

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '0'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:02:29

FDA-CBER-2022-1614-5930025

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:02:29

FDA-CBER-2022-1614-5930026

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '30 Sep 2020'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:02:29

FDA-CBER-2022-1614-5930027

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:02:29

FDA-CBER-2022-1614-5930028

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 21:02:29

FDA-CBER-2022-1614-5930029

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 21:02:29

FDA-CBER-2022-1614-5930030

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 21:02:29

FDA-CBER-2022-1614-5930031

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:16:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:16:08
Data point term sent to Coder	System	20 Nov 2020 21:15:28
User entered 'Metformin'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:14:44

FDA-CBER-2022-1614-5930032

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:14:44

FDA-CBER-2022-1614-5930033

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'DM'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:14:44

FDA-CBER-2022-1614-5930034

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '1000'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:14:44

FDA-CBER-2022-1614-5930035

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:14:44

FDA-CBER-2022-1614-5930036

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:14:44

FDA-CBER-2022-1614-5930037

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'twice daily (BID)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:14:44

FDA-CBER-2022-1614-5930038

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:14:44

FDA-CBER-2022-1614-5930039

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:14:44

FDA-CBER-2022-1614-5930040

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:14:44

FDA-CBER-2022-1614-5930041

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:14:44

FDA-CBER-2022-1614-5930042

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '1'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:14:44

FDA-CBER-2022-1614-5930043

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:14:44

FDA-CBER-2022-1614-5930044

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:14:44

FDA-CBER-2022-1614-5930045

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:14:44

FDA-CBER-2022-1614-5930046

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	20 Nov 2020 21:14:44

FDA-CBER-2022-1614-5930047

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 21:14:44

FDA-CBER-2022-1614-5930048

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 21:14:44

FDA-CBER-2022-1614-5930049

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:05
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:05
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
Data point term sent to Coder	System	20 Nov 2020 21:21:41
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:21:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:19:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:19:08
Data point term sent to Coder	System	20 Nov 2020 21:18:37
User entered 'Trazodone'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:18:18

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:18:18

FDA-CBER-2022-1614-5930051

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'ANXIETY and depression' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:21:17
User entered 'anxiety'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:18:18

FDA-CBER-2022-1614-5930052

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '100'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:18:18

FDA-CBER-2022-1614-5930053

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:18:18

FDA-CBER-2022-1614-5930054

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:18:18

FDA-CBER-2022-1614-5930055

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'once daily (QD)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:18:18

FDA-CBER-2022-1614-5930056

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:18:18

FDA-CBER-2022-1614-5930057

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:18:18

FDA-CBER-2022-1614-5930058

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:18:18

FDA-CBER-2022-1614-5930059

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:18:18

FDA-CBER-2022-1614-5930060

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '1'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:18:18

FDA-CBER-2022-1614-5930061

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:18:18

FDA-CBER-2022-1614-5930062

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:18:18

FDA-CBER-2022-1614-5930063

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:18:18

FDA-CBER-2022-1614-5930064

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 21:18:18

FDA-CBER-2022-1614-5930065

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 21:18:18

FDA-CBER-2022-1614-5930066

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 21:18:18

FDA-CBER-2022-1614-5930067

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:38:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:38:03
Data point term sent to Coder	System	20 Nov 2020 21:21:41
User entered 'Mirtazapine'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:21:07

FDA-CBER-2022-1614-5930068

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:21:07

FDA-CBER-2022-1614-5930069

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'depression'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:21:07

FDA-CBER-2022-1614-5930070

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '30'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:21:07

FDA-CBER-2022-1614-5930071

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:21:07

FDA-CBER-2022-1614-5930072

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:21:07

FDA-CBER-2022-1614-5930073

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'once daily (QD)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:21:07

FDA-CBER-2022-1614-5930074

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:21:07

FDA-CBER-2022-1614-5930075

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:21:07

FDA-CBER-2022-1614-5930076

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:21:07

FDA-CBER-2022-1614-5930077

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:21:07

FDA-CBER-2022-1614-5930078

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '1'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:21:07

FDA-CBER-2022-1614-5930079

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:21:07

FDA-CBER-2022-1614-5930080

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:21:07

FDA-CBER-2022-1614-5930081

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:21:07

FDA-CBER-2022-1614-5930082

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 21:21:07

FDA-CBER-2022-1614-5930083

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 21:21:07

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 21:21:07

FDA-CBER-2022-1614-5930085

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:27:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:27:07
Data point term sent to Coder	System	20 Nov 2020 21:26:45
User entered 'Ibuprofen'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:26:44

FDA-CBER-2022-1614-5930086

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:26:44

FDA-CBER-2022-1614-5930087

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'unknown'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:26:44

FDA-CBER-2022-1614-5930088

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '200'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:26:44

FDA-CBER-2022-1614-5930089

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:26:44

FDA-CBER-2022-1614-5930090

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:26:44

FDA-CBER-2022-1614-5930091

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'other (OTHER)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:26:44

FDA-CBER-2022-1614-5930092

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '8x daily'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:26:44

FDA-CBER-2022-1614-5930093

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:26:44

FDA-CBER-2022-1614-5930094

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:26:44

FDA-CBER-2022-1614-5930095

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:26:44

FDA-CBER-2022-1614-5930096

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '1'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:26:44

FDA-CBER-2022-1614-5930097

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:26:44

FDA-CBER-2022-1614-5930098

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:26:44

FDA-CBER-2022-1614-5930099

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:26:44

FDA-CBER-2022-1614-5930100

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:26:44

FDA-CBER-2022-1614-5930101

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:26:44

FDA-CBER-2022-1614-5930102

US3432202
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 26 Nov 2020 09:27:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:26:44

FDA-CBER-2022-1614-5930103

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 26 Nov 2020 09:27:13
Were any concomitant procedures performed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:03:17
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:33:35

FDA-CBER-2022-1614-5930104

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 26 Nov 2020 09:27:13
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:38
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered '20 Aug 2020'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:39:33

FDA-CBER-2022-1614-5930105

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 26 Nov 2020 09:27:13
Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:40
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered 'FOREIGN BODY REMOVAL from foot' reason for change: Data Entry Error	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:39:48
User entered 'Foreign body removal'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:39:33

FDA-CBER-2022-1614-5930106

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:44
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered 'Adverse Event (AE)'	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:39:33

FDA-CBER-2022-1614-5930107

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 26 Nov 2020 09:27:13
If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:46
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	27 Aug 2020 22:39:33

FDA-CBER-2022-1614-5930108

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 26 Nov 2020 09:27:13
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered '25 Sep 2020'	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 19:15:14

FDA-CBER-2022-1614-5930109

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 26 Nov 2020 09:27:13
Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered 'CT Head and Neck' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 19:16:10
User entered 'Confusion'	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 19:15:14

FDA-CBER-2022-1614-5930110

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 19:15:14

FDA-CBER-2022-1614-5930111

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 26 Nov 2020 09:27:13
If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered empty.	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 19:15:14

FDA-CBER-2022-1614-5930112

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 26 Nov 2020 09:27:13
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered '25 Sep 2020'	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 19:15:37

FDA-CBER-2022-1614-5930113

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 26 Nov 2020 09:27:13
Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered 'MRI Brain'	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 19:15:37

FDA-CBER-2022-1614-5930114

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 19:15:37

FDA-CBER-2022-1614-5930115

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 26 Nov 2020 09:27:13
If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered empty.	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 19:15:37

FDA-CBER-2022-1614-5930116

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 26 Nov 2020 09:27:13
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered '28 Sep 2020'	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 19:15:53

FDA-CBER-2022-1614-5930117

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 26 Nov 2020 09:27:13
Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered 'MRI Neck'	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 19:15:53

FDA-CBER-2022-1614-5930118

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 19:15:53

FDA-CBER-2022-1614-5930119

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 26 Nov 2020 09:27:13
If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered empty.	Monica Feeley (b) (4) (b) (4)	19 Oct 2020 19:15:53

FDA-CBER-2022-1614-5930120

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 26 Nov 2020 09:27:13
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:33
User closed query 'Per AE narrative and discharge summary CXR was done on 25sep20, please check and edit.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:46:32
Query 'Per AE narrative and discharge summary CXR was done on 25sep20, please check and edit.' answered with 'udpated' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:42:12
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:42:08
User entered '25 Sep 2020' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:42:08
User opened query 'Per AE narrative and discharge summary CXR was done on 25sep20, please check and edit.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 20:10:22
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered '29 Sep 2020'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 14:41:26

FDA-CBER-2022-1614-5930121

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 26 Nov 2020 09:27:13
Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered 'Chest X-Ray'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 14:41:26

FDA-CBER-2022-1614-5930122

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 14:41:26

FDA-CBER-2022-1614-5930123

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 26 Nov 2020 09:27:13
If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 14:41:26

FDA-CBER-2022-1614-5930124

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (6)
Generated On: 26 Nov 2020 09:27:13
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered '25 Sep 2020'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 14:49:49

FDA-CBER-2022-1614-5930125

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (6)
Generated On: 26 Nov 2020 09:27:13
Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered 'ECG'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 14:49:49

FDA-CBER-2022-1614-5930126

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (6)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 14:49:49

FDA-CBER-2022-1614-5930127

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (6)
Generated On: 26 Nov 2020 09:27:13
If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 14:49:49

FDA-CBER-2022-1614-5930128

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (7)
Generated On: 26 Nov 2020 09:27:13
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered '29 Sep 2020'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 14:50:02

FDA-CBER-2022-1614-5930129

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (7)
Generated On: 26 Nov 2020 09:27:13
Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered 'EEG'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 14:50:02

FDA-CBER-2022-1614-5930130

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (7)
Generated On: 26 Nov 2020 09:27:13
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 14:50:02

FDA-CBER-2022-1614-5930131

US3432202
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (7)
Generated On: 26 Nov 2020 09:27:13
If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered empty.	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 14:50:02

FDA-CBER-2022-1614-5930132

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:37
User entered 'USA-US078-2020-MRNA-1273-P301000003'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930133

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930134

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930135

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930136

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930137

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930138

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930139

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930140

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Lindsey'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930141

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Baden'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930142

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'MA'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930143

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:29:30
User entered 'US'	System	28 Sep 2020 12:53:51

FDA-CBER-2022-1614-5930144

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	11 Nov 2020 21:47:49
User entered '4'	System	30 Oct 2020 19:34:48
User entered '3'	System	20 Oct 2020 16:18:13
User entered '2'	System	05 Oct 2020 13:29:38
User entered '1'	System	28 Sep 2020 12:53:51

FDA-CBER-2022-1614-5930145

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:37
User entered 'USA-US078-2020-MRNA-1273-P301000003'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930146

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930147

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930148

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930149

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930150

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930151

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930152

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930153

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Lindsey'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930154

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Baden'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930155

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'MA'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930156

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:29:30
User entered 'US'	System	28 Sep 2020 12:53:51

FDA-CBER-2022-1614-5930157

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	11 Nov 2020 21:47:49
User entered '4'	System	30 Oct 2020 19:34:48
User entered '3'	System	20 Oct 2020 16:18:13
User entered '2'	System	05 Oct 2020 13:29:38
User entered '1'	System	28 Sep 2020 12:53:51

FDA-CBER-2022-1614-5930158

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form (1)
Generated On: 26 Nov 2020 09:27:13
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
User entered '28/Sep/2020 08:53'	System	28 Sep 2020 12:53:51

FDA-CBER-2022-1614-5930159

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form (1)
Generated On: 26 Nov 2020 09:27:13
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:29:30
User entered '1'	(b) (4), (b) (6)	28 Sep 2020 12:53:51

FDA-CBER-2022-1614-5930160

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:37
User entered 'USA-US078-2020-MRNA-1273-P301000003'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930161

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930162

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930163

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930164

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930165

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930166

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930167

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930168

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Lindsey'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930169

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Baden'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930170

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'MA'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930171

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:29:30
User entered 'US'	System	28 Sep 2020 12:53:51

FDA-CBER-2022-1614-5930172

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	11 Nov 2020 21:47:49
User entered '4'	System	30 Oct 2020 19:34:48
User entered '3'	System	20 Oct 2020 16:18:13
User entered '2'	System	05 Oct 2020 13:29:38
User entered '1'	System	28 Sep 2020 12:53:51

FDA-CBER-2022-1614-5930173

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form (2)
Generated On: 26 Nov 2020 09:27:13
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
User entered '05/Oct/2020 09:29'	System	05 Oct 2020 13:29:38

FDA-CBER-2022-1614-5930174

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:27:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:18:02
User entered '1'	(b) (4), (b) (6)	05 Oct 2020 13:29:38

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:37
User entered 'USA-US078-2020-MRNA-1273-P301000003'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930176

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930177

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930178

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930179

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930180

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930181

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930182

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930183

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Lindsey'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930184

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Baden'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930185

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'MA'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930186

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:29:30
User entered 'US'	System	28 Sep 2020 12:53:51

FDA-CBER-2022-1614-5930187

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	11 Nov 2020 21:47:49
User entered '4'	System	30 Oct 2020 19:34:48
User entered '3'	System	20 Oct 2020 16:18:13
User entered '2'	System	05 Oct 2020 13:29:38
User entered '1'	System	28 Sep 2020 12:53:51

FDA-CBER-2022-1614-5930188

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form (3)
Generated On: 26 Nov 2020 09:27:13
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
User entered '20/Oct/2020 16:18'	System	20 Oct 2020 16:18:13

FDA-CBER-2022-1614-5930189

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form (3)
Generated On: 26 Nov 2020 09:27:13
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:18:17
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 16:18:13

FDA-CBER-2022-1614-5930190

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:37
User entered 'USA-US078-2020-MRNA-1273-P301000003'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930191

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930192

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930193

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930194

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930195

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930196

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930197

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930198

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Lindsey'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930199

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Baden'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930200

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'MA'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930201

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:29:30
User entered 'US'	System	28 Sep 2020 12:53:51

FDA-CBER-2022-1614-5930202

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	11 Nov 2020 21:47:49
User entered '4'	System	30 Oct 2020 19:34:48
User entered '3'	System	20 Oct 2020 16:18:13
User entered '2'	System	05 Oct 2020 13:29:38
User entered '1'	System	28 Sep 2020 12:53:51

FDA-CBER-2022-1614-5930203

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form (4)
Generated On: 26 Nov 2020 09:27:13
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:17
User entered '30/Oct/2020 15:34'	System	30 Oct 2020 19:34:48

FDA-CBER-2022-1614-5930204

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:27:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:17
User entered '1'	(b) (4), (b) (6)	30 Oct 2020 19:34:48

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:37
User entered 'USA-US078-2020-MRNA-1273-P301000003'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930206

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930207

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930208

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930209

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930210

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930211

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930212

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930213

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Lindsey'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930214

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Baden'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930215

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'MA'	System	28 Sep 2020 12:53:24

FDA-CBER-2022-1614-5930216

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:29:30
User entered 'US'	System	28 Sep 2020 12:53:51

FDA-CBER-2022-1614-5930217

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 26 Nov 2020 09:27:13
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	11 Nov 2020 21:47:49
User entered '4'	System	30 Oct 2020 19:34:48
User entered '3'	System	20 Oct 2020 16:18:13
User entered '2'	System	05 Oct 2020 13:29:38
User entered '1'	System	28 Sep 2020 12:53:51

FDA-CBER-2022-1614-5930218

US3432202
Folder: SAE USA-US078-2020-MRNA-1273-P301000003
Form: Safety Report Form (5)
Generated On: 26 Nov 2020 09:27:13
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User entered '11/Nov/2020 16:47'	System	11 Nov 2020 21:47:49

FDA-CBER-2022-1614-5930219

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:27:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 21:47:49